Developing an Asia-Pacific Manufacturing Footprint Strategy in the Medical Device Industry

by

Nishanth K. Dev

B.S.E. Mechanical Engineering, Duke University, 2007

Submitted to the MIT Sloan School of Management and the Engineering Systems Division in Partial Fulfillment of the Requirements for the Degrees of

Master of Business Administration
and
Master of Science in Engineering Systems

In conjunction with the Leaders for Global Operations Program at the Massachusetts Institute of Technology

June 2013

Signature of Author _____
Engineering Systems Division, MIT Sloan School of Management
May 10, 2013

Certified by _____
Jonathan Byrnes, Thesis Supervisor
Senior Lecturer, Engineering Systems

Certified by _____
Charles Sodini, Thesis Supervisor
Clarence J. LeBel Professor, Electrical Engineering and Computer Science

Accepted by _____
Olivier de Weck, Chair, Engineering Systems Education Committee
Associate Professor, Aeronautics and Astronautics and Engineering Systems

Accepted by _____
Maura Herson, Director of MIT Sloan MBA Program
MIT Sloan School of Management

This page intentionally left blank.

Developing an Asia-Pacific Manufacturing Footprint Strategy in the Medical Device Industry

by

Nishanth K. Dev

Submitted to the MIT Sloan School of Management and the Engineering Systems Division on May 10, 2013 in Partial Fulfillment of the Requirements for the Degrees of Master of Business Administration and Master of Science in Engineering Systems

Abstract

As medical device manufacturers operating in the Asia-Pacific region are planning for increased demand in the near future, they must evaluate their manufacturing footprint strategies to determine if they are getting the most value out of their supply chains given the various incentives and costs associated with regional manufacturing. Company X is investigating manufacturing expansion opportunities for medical devices due to the significant revenue growth rates expected for the Asia-Pacific region, especially in the emerging markets. This thesis deals with the development of a repeatable methodology that can be used to evaluate various medical device products and manufacturing capabilities for Asia-Pacific sourcing. The methodology was tested on a selected subsidiary to determine if a regional manufacturing opportunity exists. Furthermore, a business process, which includes insights into data collection, team formation, and implementation of footprint decisions, was developed for Company X to use in determining its overall network strategy for the sector. Other manufacturers can apply the methodology and the business process in the development of their manufacturing footprint strategies as well. Although the results from the decision analysis did not favor expansion of the manufacturing operations for the selected Product Line B in the Asia-Pacific region, they helped in identifying the key factors that would favor regional expansion. In addition, crucial factors that may be difficult to quantify, such as intellectual property rights, must be considered before making a expansion decision, even if it is the favored outcome based on the results of the decision analysis for other product lines or subsidiaries.

Thesis Supervisor: Jonathan Byrnes
Title: Senior Lecturer, Engineering Systems

Thesis Supervisor: Charles Sodini
Title: Clarence J. LeBel Professor, Electrical Engineering and Computer Science

This page intentionally left blank.

Acknowledgments

I would first like to thank Company X for sponsoring this project. It was both challenging and rewarding, and I am sure that I will be able to apply what I learned over the course of my career. I especially want to thank my supervisor for his support and guidance from start to finish. I also want to thank the company's management team for their support of the LGO Program and this project. A special thanks to my colleagues and everybody who helped me gather the data that I needed over the course of the project as well.

I also want to thank the Leaders for Global Operations Program for providing me with this wonderful opportunity over the past two years. I especially want to thank my thesis advisors, Jonathan Byrnes and Charlie Sodini, for their guidance and encouragement over the course of the project. I promise that my e-mails will be shorter from this point onwards! To my friends at MIT – great times were had while we were together! Thanks for all of the laughs, the homework help, and most importantly, your friendship. I also want to take this opportunity to thank two of my roommates – Bart Oliver and Kjell Wangensteen. It was a pleasure living with you guys while I completed this project, and I will certainly let you know if I am ever in town.

Last, but not least, I want to thank my family for their love and constant support. Mom and Dad – you are the best parents that I could have asked for, and I hope that I have made you both proud. Sis – your best days are yet to come, so keep plugging away and good things will happen. Wherever we are in this world, we will always be a family.

This page intentionally left blank.

Table of Contents

List of Figures

List of Tables

1 Introduction

This chapter defines the problem statement and presents the research methodology used in the evaluation of the problem, objectives of the evaluation, and an overview of both Company X and the medical device industry. The chapter summary, which is presented in the last section, provides an outline of the entire thesis.

1.1 Problem Statement

With the expected growth of the medical device industry in the Asia-Pacific region, especially in emerging markets such as China and India, many manufacturers are developing strategies to take full advantage of the situation from a supply chain perspective. Company X, in particular, is assessing the risks and benefits of increasing the regional presence of its manufacturing and supply chain operations in order to increase its responsiveness to market demands more rapidly. The goal of this project was to develop a repeatable methodology and a business process that can be used to evaluate medical device products and manufacturing capabilities exploiting regional sourcing opportunities. The developed methodology was tested on a selected range of products from a subsidiary of Company X to determine if a regional manufacturing opportunity exists with the given forecasts as well as various uncertainties.

1.2 Research Methodology & Objectives

In order to develop a repeatable methodology and an appropriate business process, a variety of sources were used. Research literature reviews and stakeholders interviews were used to identify the key criteria needed to determine what products are suitable for manufacturing in Asia-Pacific, the method of production (i.e., internal manufacturing or outsourcing), and how to evaluate locations for manufacturing

operations. The macroeconomic and project risk factors that should be accounted for in the decision analysis were also identified in a similar manner. In a parallel effort, the product lines for a selected franchise were evaluated using the risk factors, sales, and capacity forecasts to determine if manufacturing opportunities existed in various regional locations and what the best option for expansion would be in various scenarios. In addition, an evaluation of a key process technology used by Company X was completed to illustrate an example for determining when a process technology is considered a trade secret and what steps should be taken to protect intellectual property (IP). The research conducted was completed in order to meet the following objectives:

- Determine the key decision factors needed from a manufacturing footprint strategy in the Asia-Pacific region and incorporate them into a repeatable methodology
- Formulate a business process to show how the decision factors should be treated in order to make informed decisions for manufacturing footprint decisions
- Demonstrate how various decision analysis tools (e.g., net present value calculations, landed cost analysis, sensitivity analysis) can be used to identify the best option(s)
- Identify the considerations for determining products and processes with IP sensitivity and illustrate how they can be applied, with a case example using a current process technology
- Provide recommendations and topics for further evaluation based on the research conducted and outcomes

1.3 Company Overview

Company X is a diversified health care company that operates in more than 60 countries worldwide. The company develops, manufactures, and markets a variety of products ranging from pharmaceutical products to orthopedic devices. It is made up of a number of subsidiaries, each of which is responsible for developing and marketing a distinct set of products.

Company X's organizational structure is primarily based on the decentralized principle for management. Each of the primary subsidiaries used to operate independently and manage their own revenues and costs. However, in 2010, the primary manufacturing and supply chain operations for each of the subsidiaries were removed from their respective organizations and re-organized into a separate division. This organization works with the different subsidiaries to ensure product supply, develop strategies to reduce operating costs, and mitigate supply risks. Executive leaders anticipated that the shift would significantly help in aligning all of the manufacturing and supply chain operations to similar quality standards throughout the network and improve end-customer relationships overall. For each of the three major product divisions (denoted as Divisions A, B, and C in this thesis), there is an executive leader and team responsible for the manufacturing and supply chain operations of that business segment. Figure 1 provides a high-level overview of the organizational structure for the Company X's new supply chain division as follows (note: this organizational chart only includes the groups within the division that are referenced in this thesis, and there are other groups that are not included in this figure):

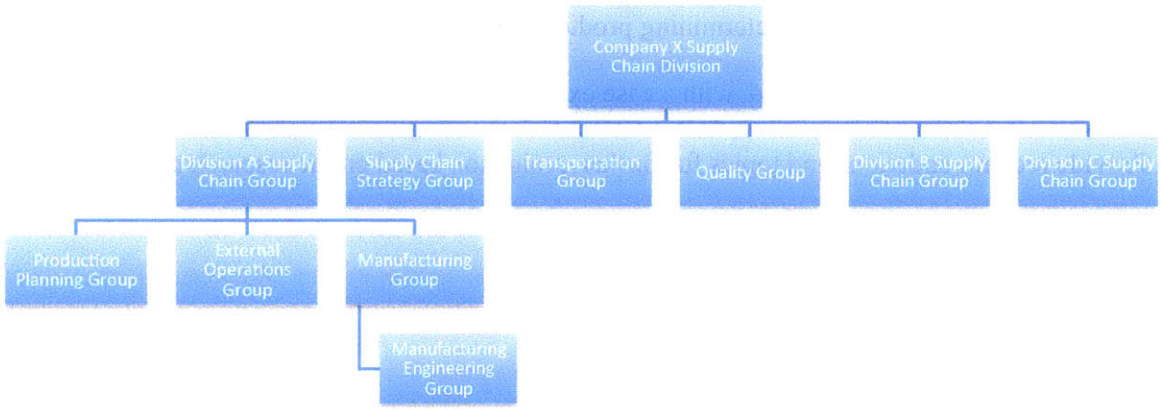


Figure 1 - High-Level Organizational Structure of the Supply Chain Division

The Division A Supply Chain Group is responsible for these operations across the medical device subsidiaries. This group is referred to as "the" Supply Chain Group throughout this thesis. There are also a number of groups that support various other functions in addition to the Supply Chain Group, including

Finance, Legal Affairs, and Human Resources (HR). In addition, each subsidiary has retained various manufacturing and supply chain personnel to coordinate efforts between the Supply Chain Group and the various commercial (i.e., sales and marketing) and Research & Development (R&D) functions for that subsidiary. This group is called the Subsidiary Operations Development Group and resides within the subsidiary.

1.4 Industry Overview

Although medical devices have existed for centuries, the industry has only been recognized within the last century. The U.S. Food and Drug Administration (FDA), which is the regulatory agency for medical devices and diagnostics in the United States, defines a medical device as "an instrument, apparatus, implement, in vitro reagent, or other similar or related article, including a component part, or accessory, which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." (Food & Drug Administration, 2012)

Medical devices include a variety of products ranging from sutures to blood glucose monitors and orthopedic implants. Diagnostics are also included under this definition. While the FDA is one of the oldest and most respected regulatory agencies of its kind, most countries have their own rules and regulations for the manufacturing, marketing, and distribution of medical devices within its territories.

The global market for the medical devices industry was valued at nearly $238 billion in 2011 and is expected to grow 5.1% annually till 2015 (Frost & Sullivan, 2012).

1.5 Chapter & Appendix Summary

The following is a summary of the chapters and appendices that are included in this thesis document:

- Chapter 2 provides details of the project motivation, focusing on the expected growth in the Asia-Pacific region, Company X's current supply operations in the region, and the need for both a methodology and a business process.
- Chapter 3 describes the methodology that can be applied in determining what products are suitable candidates for regional sourcing, where the products could be manufactured, and how supply operations should be considered. Given the decisions made in each segment, decision analysis tools can be applied in order to determine the best path forward.
- Chapter 4 gives an overview of the business process that medical device manufacturers can use in applying the methodology and how to organize and manage the process. An overview of how the business process can be applied at Company X is also shown.
- Chapter 5 provides insights to the IP rights and considerations that should be made when considering a manufacturing expansion in the Asia-Pacific region. This chapter focuses on trade secret protection, and an example of a process technology at Company X is evaluated. In addition, the chapter has an overview of the valuation of a trade secret loss.
- Chapter 6 includes a case study in which the methodology is applied to product lines of a subsidiary at Company X. In addition to applying the tools, the results of the decision analysis are provided along with a sensitivity analysis.

- Chapter 7 builds on the results from the case study to provide further considerations in the manufacturing footprint strategy development sphere and potential next steps for the Supply Chain Group at Company X.
- Appendix A lists all equations, uncertainties, and risk factors that were applied during the case study.
- Appendix B includes the data set(s) that were analyzed as part of the case study as well as summary notes for each of the decision analysis tools.

2 Project Motivation

This chapter addresses why Company X and other medical device manufacturers are interested in expanding its supply chain operations in the Asia-Pacific region. The motivation for this project should be viewed as the first step in the development of the regional manufacturing footprint strategy as discussed by Christodoulou, Fleet, Hanson, Phaal, Probert, & Shi (2007). Figure 2 highlights "why" a medical device manufacturer would want to develop a manufacturing footprint strategy in the Asia-Pacific region (original figure from Christodoulou et al., 2007, p. 10):

- Market Demand
- Build Customer Relationships & Supply Chain Responsiveness
- Government Incentives
- Potential to Spur Innovation & Take Advantage of Existing Technical Capabilities
- Financial Incentives

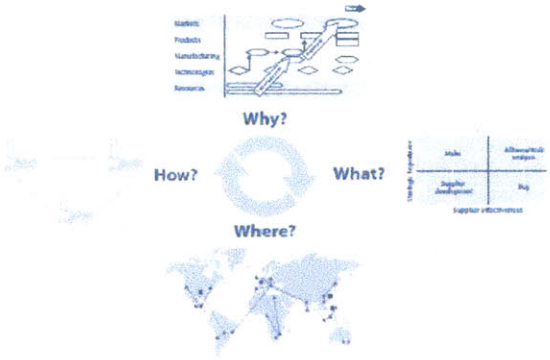


Figure 2 - "Why" to Develop a Location-Specific Manufacturing Footprint Strategy

In this chapter, we review the expected regional market growth and briefly assess the Supply Chain Group's current regional operations. Then, we evaluate the benefits and the risks of the Asia-Pacific expansion opportunities based on literature research and interviews with key stakeholders across Company X. This evaluation leads to the need for a repeatable methodology and a rigorous business process for the group. Further details of the applied methodology ("What", "Where", and "How") are discussed in Chapter 3.

2.1 Market Growth in the Asia-Pacific Region

Company X is very interested in increasing its market access for the Asia-Pacific region based on the anticipated growth rates, especially in emerging markets such as China and India. Figure 3 illustrates the expected growth of the medical device industry in the Asia-Pacific region compared to the rest of the world (Frost & Sullivan, 2012):

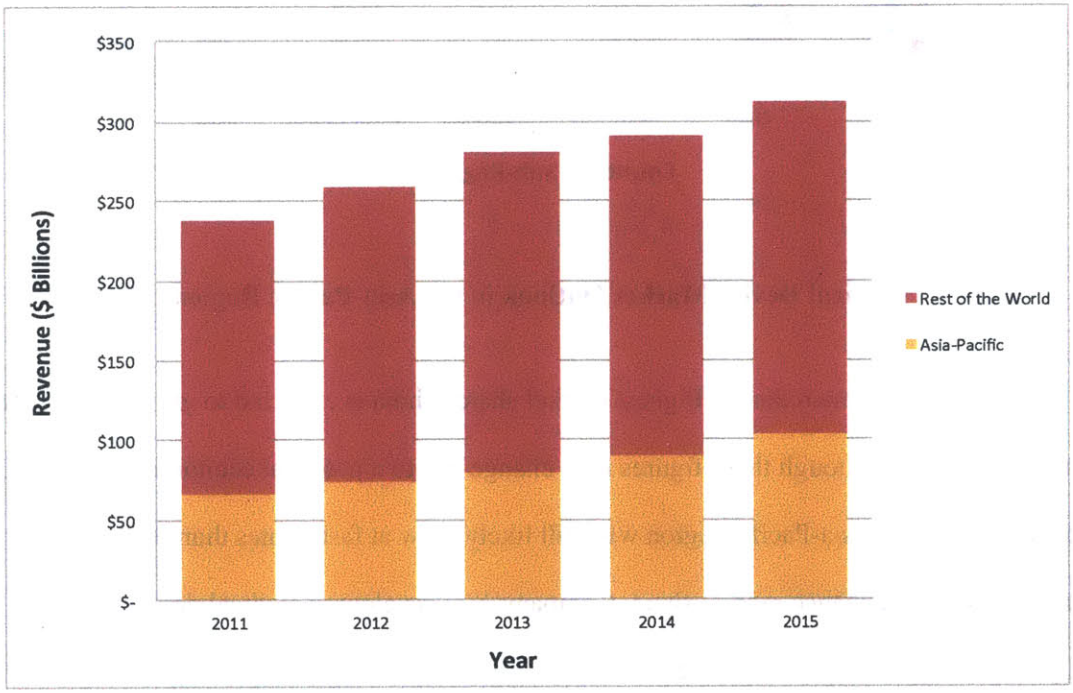


Figure 3 - Worldwide Medical Device Market Outlook till 2015

The medical device industry in Asia-Pacific is expected to grow at a cumulative annual growth rate (CAGR) of 11.6% till 2015, which is more than double the global growth rate of 5.1%. Based on the same report, the Asia-Pacific region will account for 33.2% of the global medical device market in 2015. The primary growth drivers are an aging population and access to new surgical options for patients in these markets (Frost & Sullivan, 2012).

Within the Asia-Pacific region, the developing markets are expected to have the highest growth rates as evidenced in Figure 4 below (Frost & Sullivan, 2012):

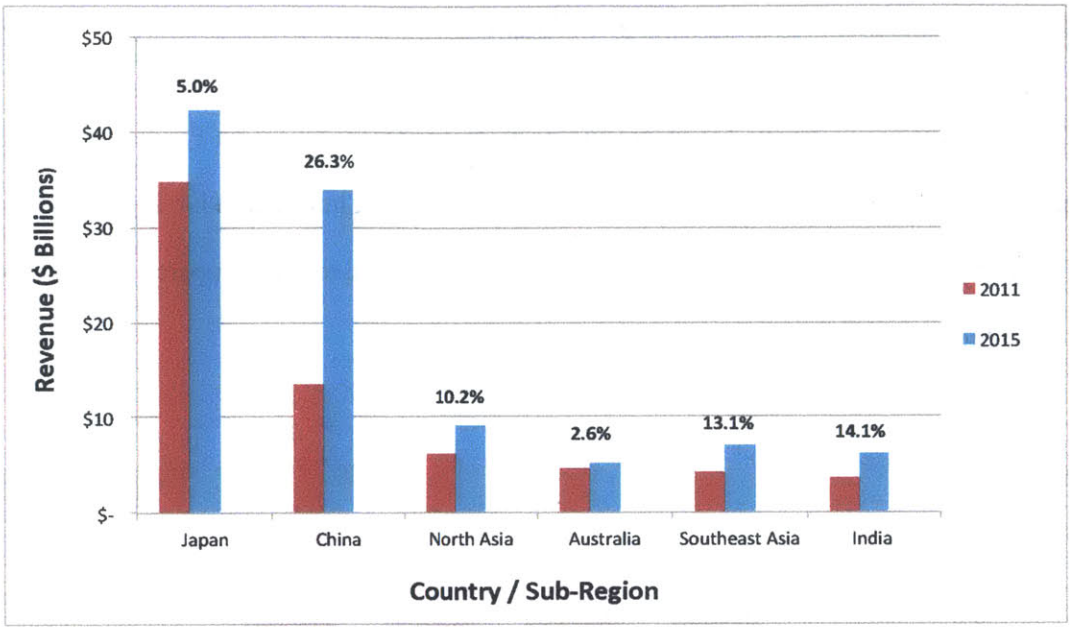


Figure 4 - Medical Device Market Outlook in the Asia-Pacific Region till 2015

While Japan is expected to maintain the highest market share, China is expected to grow significantly over the next few years. Although these figures may change due to a potential economic slowdown, the developing nations in the Asia-Pacific region will still likely grow at faster rates than its developed counterparts. In order to enhance market share, Company X is developing medical devices that are geared specifically for the needs of those customers.

Donoghoe, Gupta, Linden, Mitra, and Von Morgenstern (2012) argue that companies attempting to market and sell their current product lines in developing markets have not been as successful as anticipated. The customer needs in the developing countries, especially the suburban and rural areas, are different from what a company's traditional offerings are, and product cost still remains a key driver. In 2008, various subsidiaries within Company X embarked on an R&D project to develop low-cost medical devices that would meet these customers' needs. Aptly nicknamed "market-appropriate products", they are currently being developed, tested, and sold in China. One of the differences between the market-appropriate products and the original products being sold include the use of metal parts in order for devices to be cleaned, sterilized, and re-used. Company X is paying particular attention to whether it is

more appropriate to manufacture these products closer to its intended customers as part of its Asia-Pacific manufacturing footprint strategy. This is in addition to other devices with similar manufacturing platforms that could also be produced using the same unit operations.

2.2 Current Medical Device Supply Operations in the Region for Company X

The Supply Chain Group currently has a limited presence in the Asia-Pacific region when compared to its presence in North America and Europe. The following is a list of the internal medical device and diagnostic manufacturing sites in the Asia-Pacific region and the main product lines produced at each location:

- China – Implants & Medical Devices
- India – Liquids & Medical Devices
- Pakistan – Liquids & Medical Devices
- Japan – Liquids

Less than 5% of the medical devices and diagnostics sold in the region are manufactured at all of these facilities combined. Of the current locations, the Supply Chain Group generally sees the most opportunities for expansion at its current sites in China and India. In addition to potentially developing its internal manufacturing capabilities, the group will also be expanding its regional distribution center in Singapore over the next two years. Singapore was chosen because of the number of company executives that currently work in the country and the opportunity to gain broader access to the Asia-Pacific markets in general. The plan is to manage the inventory for the entire region from a single location rather than rely on multiple distribution centers. As a result, the medical device manufacturing sites in the internal network will be required to send all manufactured products to the Singapore location, even if it means that

some of those products will be sold in the country of manufacture. This strategy could be reevaluated with additional changes to the regional manufacturing footprint.

The Supply Chain Group has relationships with a number of suppliers and third-party manufacturers in the region. Certain subsidiaries, however, have more ties to suppliers and contract manufacturers in the Asia-Pacific region than others. Although the group is not actively expanding its regional supplier base at this time, it is working with its current regional suppliers to minimize costs and ensure quality. For example, the External Operations Group, which is responsible for managing third-party manufacturing within the Supply Chain Group, is looking into the possibility of establishing a branch location in the Asia-Pacific region to strengthen its relationships with its regional contract manufacturers. While the primary focus of this thesis is on the internal manufacturing footprint strategy development, the potential outsourcing opportunities are also taken into consideration where appropriate.

2.3 Benefits & Risks to Manufacturing Medical Devices in the Asia-Pacific Region

Across Company X, there are different views as to benefits and risks of conducting manufacturing operations in the Asia-Pacific region. In order to gain a better understanding of the various views, I conducted 23 interviews with key stakeholders that were involved in the analysis of regional opportunities. They were asked to identify the benefits and risks of having a manufacturing presence in the Asia-Pacific region. These factors are integrated into the methodology presented in Chapter 3. The potential benefits of manufacturing in the region, as identified through the various interviews and subsequent literature research, are as follows:

1. Build Stronger Customer Relationships & Supply Chain Responsiveness

   In the past, Company X has been successful at developing strong relationships with customers and regulatory agencies by establishing a manufacturing presence in various locations. Such a

presence allowed them to make process modifications based on customer input much faster. For example, an operations leader overseeing the medical device manufacturing strategy for the Asia-Pacific region noted that there could be potential changes to labeling requirements as part of Chinese State Food and Drug Administration (SFDA) Regulation 276 in 2013 that would require devices to be labeled in the appropriate language prior to being shipped to China. Most labels are currently placed on product boxes at a facility in China. Having an existing facility in the region that can conduct labeling operations outside of China would ease the burden of meeting this requirement if the change were instituted. While decreases in lead time and a reduced probability of local stockouts can occur due to proximity of the manufacturing and distribution facilities, much of it is also dependent on supplier locations and their ability to meet demand at each manufacturing location.

2. Government Incentives

Currently, there are no governments in the Asia-Pacific region that require a company to have a local manufacturing presence in order to market and sell products in that country. However, there is no guarantee that this precedence will not change over time. For example, as part of its Pharma 2020 Plan, the Russian government is requiring pharmaceutical and medical device companies to domestically manufacture at least 50% of the products that it intends to sell in the country (Frost & Sullivan, 2011). In addition, governments could always increase duties on imported medical devices in an effort to promote in-country manufacturing. Company X would be in a better position if a manufacturing presence were already established and such actions were taken.

3. Potential to Spur Innovation & Take Advantage of Existing Technical Capabilities

Company X has established R&D centers in China and India to help in the development of market-appropriate products. Two senior manufacturing managers believe that having a

manufacturing presence will have a similar effect on innovation. Moreover, two stakeholders are strong advocates of the Supply Chain Group taking advantage of the current technology centers of excellence in the region as part of the manufacturing footprint strategy.

4. Financial Incentives

The traditional incentives for manufacturing in certain locations in the Asia-Pacific region include lower labor and overhead costs in certain countries (e.g., parts of China and India). Furthermore, if fuel prices continue to increase, local manufacturing could lead to lower transportation costs and become yet another incentive. Company X is focusing their efforts on regional market access with costs savings being a secondary consideration.

While these benefits could certainly help any medical device manufacturer, they are not without various risks. The same stakeholders identified the following risks in the regional footprint development process:

1. Developing Talent & Operating Capabilities in the Region

Since the Supply Chain Group does not have a strong regional presence, there will need to be significant investments in building facilities and developing management talent. Six of the 18 stakeholders interviewed from the group pointed to the difficulty with developing and retaining talent in China due to the high turnover rate. Moreover, this is not unique to Company X. Powell (2012) notes that some companies in the biotech and pharmaceutical industries currently have turnover rates close to 50% at their locations in China.

2. Changing Regulations in Countries Throughout the Region

The regulatory agencies in the region have not been in existence as long as agencies such as the U.S. FDA. Consequently, they are still developing their policies with respect to device

registration and trial requirements. Sixteen of the 23 stakeholders interviewed across Company X specifically commented on the clinical trial requirements in China as a barrier to entry. Based on the current interpretation of the rules from the SFDA, a majority of Class II products will require clinical testing through trials if the devices are manufactured in China with the intention of selling and distributing them in the country. However, this rule does not apply for the same devices that are manufactured elsewhere (i.e., outside of China) and then exported there for commercial purposes. The same group of stakeholders also noted that this rule could be changed by the SFDA at any time.

3. Intellectual Property Rights

Even though there are countries in the Asia-Pacific region with strong IP protection in general, the same cannot be said for many developing countries in the region with the higher expected growth rates. Company X is very cautious of placing processes required strong IP protection in certain countries. This issue is explained in greater detail in Chapter 5.

2.4 The Need for a Methodology and a Business Process

Given the expected revenue growth and the limited medical device manufacturing presence in the Asia-Pacific region, the Supply Chain Group is looking for a way to evaluate its manufacturing opportunities to determine if it makes sense to source certain medical devices from the region. On the other hand, it could be more cost-effective and beneficial to continue sourcing products from current manufacturing locations in its network. In order to make the best decisions, a comprehensive and repeatable methodology must be used. In the past, each of the primary subsidiaries at Company X was responsible for investigating its own manufacturing opportunities, and a standardized method was not applied. Opportunities that did not appropriately account for certain macroeconomic factors or combined

facility capabilities during the analyses may have been overlooked as a result. The methodology reported in this thesis takes into account the benefits and risks with manufacturing in the region in order to make the best decision. Further details regarding the risk factors to incorporate and analyze are explained in Chapter 3.4.

In addition to using a repeatable methodology, a business process is developed in order to standardize the way that the methodology was followed. It includes insights into data collection, team formation, review timeframes, and implementation of footprint decisions when following the methodology. Some of the existing decision tools at Company X can be incorporated in the business process. Further details about the process are discussed in Chapter 4.

3 A Methodology for Developing a Manufacturing Footprint Strategy

The methodology proposed in this chapter is structured similarly to the framework recommended by the Institute for Manufacturing at the University of Cambridge but is tailored for developing the footprint strategy in the Asia-Pacific region as opposed to a company's entire network. The "Why-What-Where-How" framework, as depicted in Figure 5 below, can be used to identify the possible footprint expansion options in the region (original figure from Christodoulou et al., 2007, p. 10):

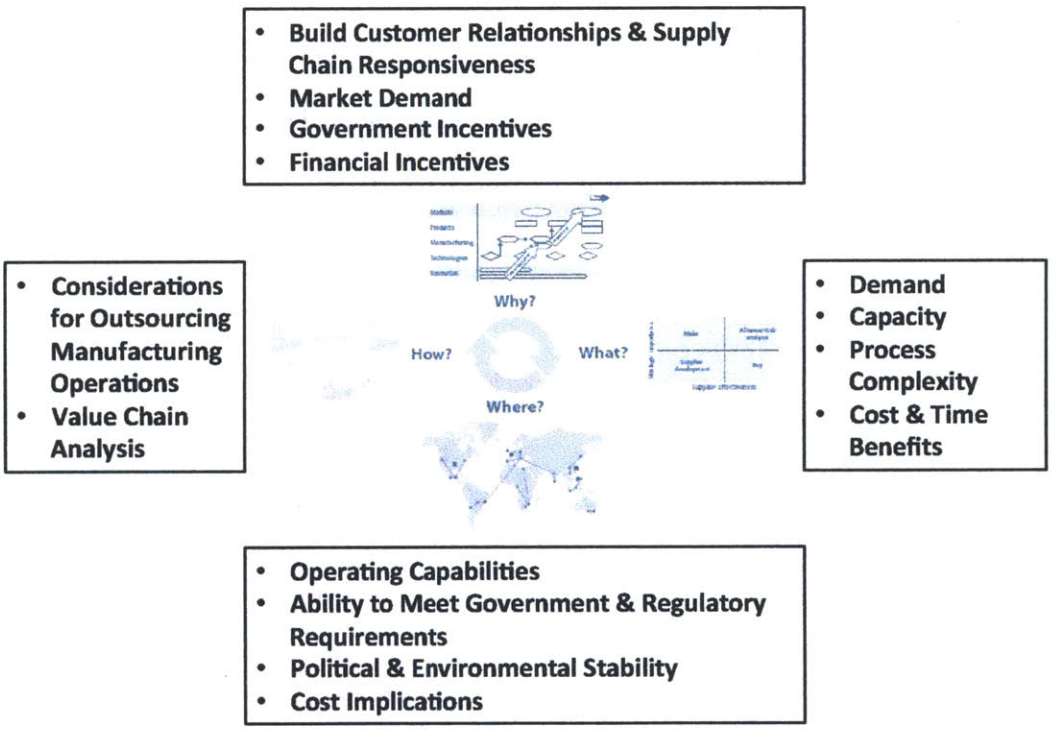


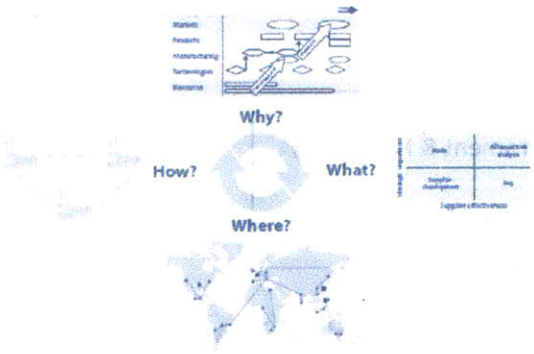
Figure 5 - Overview of the Methodology for a Medical Device Manufacturer

The "Why" part of the framework was explained in Chapter 2 as part of the company's need for the manufacturing footprint strategy in the Asia-Pacific region. The following subchapters include the structure for determining 1) what products are candidates for regional sourcing, 2) where manufacturing should take place, and 3) how the supply chain should be developed. My research with Company X helped me to develop the specific criteria for the "What" and "Where" phases. Each section includes a

modified version of Figure 5 that details the decision criteria for each phase. The specific risk factors and uncertainties to account for are also described throughout the chapter. Using the methodology should yield a variety of options with a number of manufacturing solutions. At that point, a decision analysis will be required to select the most appropriate choice. Insights into the decision analysis tools are given in the last section of this chapter.

3.1 Decision Criteria for What Products to Source

The first step is to determine what products are most suitable for sourcing in the Asia-Pacific region. The objective is to identify candidates that could be manufactured successfully in the region from a variety of products using the criteria highlighted in Figure 6 below (original figure from Christodoulou et al., 2007, p. 10):



- Demand
- Capacity
- Process Complexity
  - Regulatory Classification
  - IP Rights
  - Process Maturity
  - Operating Capabilities Required
  - Investment Required
- Cost & Time Benefits
  - Decreased Lead Times
  - Proximity to Suppliers
  - Lower Operating Costs
  - Lower Logistics Costs
  - Tax Benefits

Figure 6 - Decision Criteria for the "What" Analysis

The following is a list of criteria, developed through my industry and company research, that should be examined when evaluating a variety of products as part of the manufacturing footprint strategy development:

1. Regional & Global Demand

It is important to examine country-specific and Asia-Pacific demand to understand what the customer's needs are. Global demand should also be evaluated since it is likely that the new manufacturing facility could meet production needs to satisfy demand in other regions worldwide. Each of the subsidiaries at Company X annually creates a 7-year forecast of global and regional sales, and some subsidiaries provide sales forecasts by country. Appendix A includes an example of how the sales forecast can be translated into forecasts for demand volume (i.e., the number of units to be manufactured). Variations in both the sales and demand volume forecasts must be considered in evaluating the criterion, and they should be taken into account as part of the decision analysis. For example, large variations in the sales forecasts could yield situations where demand volume is lower than expected. Consequently, the decision to expand may not be the most suitable one.

2. Current Network Capacity

While evaluating product demand, it is also important to understand the capacity constraints at existing manufacturing locations in the network. The Supply Chain Group began translating the sales forecast data into demand volume forecasts and line utilization forecasts in 2012 with the expectation of identifying capacity needs as early as possible. Given the significant investment needed for a new facility, it generally is not worthwhile to build a new plant if an existing plant can meet demand over the forecast horizon with a lower investment cost. While capacity may exist in the network, products that are single-sourced (i.e., produced in only one location) could be viewed as a supply chain risk, especially if another backup location is not identified or available. This is another risk that should be accounted for in the decision analysis. Treleven and Bergman (1988) go into further detail regarding the benefits and costs and risks associated with single sourcing and dual sourcing.

3. Process Complexity

The required skill sets and processing needs vary among the range of product lines supported by the Supply Chain Group. The following are the criteria that should be evaluated for determining how complex it would be to complete the technology transfer and conduct manufacturing operations:

- **Regulatory Classification** – More work is generally required for devices with higher classifications. As an example, clinical trials may be required for Class 3 devices, as classified by the FDA, produced in a new location. In general, the Medical Device Supply Chain Group is more cautious about establishing manufacturing locations for Class 3 devices than Class 2 or Class 1 devices for this reason.
- **IP Rights** – It will be more difficult to transfer manufacturing processes that are considered to be trade secrets to certain locations in the Asia-Pacific region for fear of IP theft and possible counterfeiting. This is further discussed in Chapter 5.
- **Process Maturity** – Mature processes are generally characterized as those having higher and more stable yield rates, strong product and supply specifications, and minimal quality issues previously. These processes are more likely to be transferred successfully based on previous experience within the Supply Chain Group.
- **Operating Capabilities Required** – There are certain processes that may require trained expertise in order to conduct manufacturing. For instance, if a process involves training in a new skill set such as those required for biologics manufacturing, there may be a stronger need for operator capabilities (e.g., operators with technical backgrounds). On the other hand, several mechanical assembly processes used by the Supply Chain Group at various facilities do not require the same level of operating capabilities.

- **Investment Required** – The potential cost benefits (described below in Item 4) or potential revenue gain must at least make up for the initial investment. For the Supply Chain Group, different process technologies require different levels of investments. This criterion becomes considerably more important if capital is constrained in various organizations and only a certain combination of product lines is initially selected.

4. Cost & Time Benefits

There should be some major benefits to manufacturing the product in the Asia-Pacific region relative to the current manufacturing operations or, if it is a brand-new product line, where the products are initially developed (e.g., R&D facilities). The following is a list of the potential benefits that should be evaluated:

- **Decreased Lead Times** – With a new location in the region, there is an opportunity to decrease the lead times for raw material supply to the facility and finished goods to customers.
- **Proximity to Suppliers** – If the raw material suppliers for the devices being evaluated have operations in the region, there is an opportunity to strengthen relationships and potentially reduce material costs. In the past, some suppliers have located new supply operations close to the Supply Chain Group's manufacturing facilities. This could happen again if the Supply Chain Group were to expand its manufacturing footprint in the Asia-Pacific region.
- **Lower Operating Costs** – This refers to the general expenses of conducting manufacturing operations in that location, such as labor, and overhead, while accounting for the appropriate risks (e.g., long-term currency variation)
- **Lower Logistics Costs** – By producing those products in the region and not having to rely on imports, there are opportunities to take advantage of lower raw material and

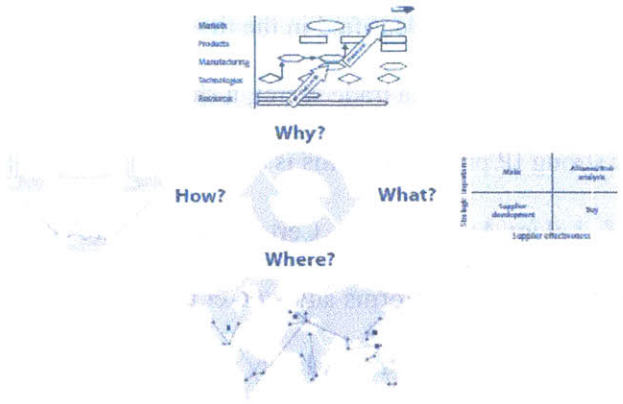
finished goods transportation costs. A producer could also take advantage of reductions in import taxes and duties through free trade agreements. Further evaluation of this potential advantage as discovered in the case study is presented in Appendix A.

- **Tax Benefits** – As previously mentioned, certain locations provide income tax incentives to companies that establish manufacturing locations there. While countries such as Singapore have low corporate tax rates in general, countries such as Malaysia offer short-term tax benefits to incentivize multinational corporations to establish a manufacturing presence (Ernst & Young, 2012). However, in certain situations, it may not be beneficial overall for a medical device manufacturer to take advantage of the tax incentive based on its overarching income tax strategy.

When evaluating the criteria above, there will likely be some overlap between the location choices and how operations should be conducted once the potential product lines are identified. These overlaps are discussed in more detail in Chapters 3.2 and 3.3.

3.2 Decision Criteria for Where to Conduct Operations

Once the products that could be successfully manufactured in the Asia-Pacific region are identified, the next step is to consider where manufacturing should take place. The objective is to identify potential locations where manufacturing should take place using the criteria as highlighted in Figure 7 below (original figure from Christodoulou et al., 2007, p. 10):



- **Operating Capabilities**
  - **IP Protection**
  - **Technology & Talent Availability**
  - **Availability of Supplier & Key Contractors**
  - **Language & Cultural Barriers**
- **Ability to Meet Government & Regulatory Requirements**
- **Political & Environmental Stability**
- **Cost Implications**

Figure 7 - Decision Criteria for the "Where" Analysis

The following is a list of criteria developed by myself through my research with Company X that should be evaluated when choosing locations as part of the manufacturing footprint strategy development:

1. Operating Capabilities

   This is the most important criterion when determining a location, based on the research conducted with the Supply Chain Group. In order to ensure quality, the right capabilities must be present. It is possible for medical device manufacturers to develop certain capabilities in remote locations over time, but there are distinct advantages to choosing locations where the infrastructure already exists. The following is a list of considerations to review when looking at the general operating capabilities of a potential location:

- **IP Protection** – If a product identified in the first stage of the methodology as a potential candidate has a process that is a trade secret, it should be placed in locations that have a reputation for strong IP protection. This is discussed in greater detail in Chapter 5.
- **Technology & Talent Availability** – Certain locations are attractive for their prominence in technology platforms and worker talent. The leadership team of the Supply Chain Group believes that it is likely to find greater success in establishing a manufacturing presence in these types of locations. Steinle and Schiele (2007) explain that firms that establish locations in industry clusters "can benefit from an increased availability of complementary products and services and have better access to suppliers, specialized employees in the local labor pool, specific information and public institutions, such as specialized education or associations" (p. 4). In addition, during the various stakeholder interviews, many stakeholders expressed an appreciation for the campus approach in establishing manufacturing locations. This entails having a variety of manufacturing processes and technologies, which are utilized to produce devices for a range of subsidiaries, in a specified location to leverage operating capabilities overall. The stakeholders in the Supply Chain Group view its campus in Mexico as highly successful for this reason. Therefore, there is a greater emphasis to establish manufacturing operations at sites where the company already has a presence.
- **Availability of Suppliers & Key Contractors** – In a similar light to the establishment of technology platforms, having suppliers and contractors in the same vicinity is major advantage in many cases. As an example, the Supply Chain Group is reviewing its sterilization capabilities and trying to establish better relationships with specific sterilization contractors across all product sectors. The locations of these contractors in the Asia-Pacific region may rule out certain locations due to the importance of sterilization in the manufacturing process, assuming that the sterilization process required for the product lines is not considered a core competency.

- **Language & Cultural Barriers** – While these may not be avoided completely, it would be advantageous to establish a manufacturing presence in a location where language and cultural barriers will not become an issue.

2. Ability to Meet Regulatory & Government Requirements

All medical device manufacturers must work with the regulatory and government agencies of the countries that it intends to market products in, and they should not assume that the regulations of another agency (e.g., the U.S. FDA) supersede the local regulations. If certain agencies require healthcare companies to have an in-country manufacturing presence, companies must evaluate the products that they intend to sell within the country and also evaluate the operating capabilities of that country to determine the best product manufacturing fit(s). The imposed domestic manufacturing requirement in Russia that was discussed in Chapter 2.3 is the latest example of this potential trend. Established manufacturing operations must also work with other government agencies, such as those responsible for labor and environmental policy, in order to be successful.

3. Political & Environmental Stability

It is preferable to establish a manufacturing presence in locations where political and environmental stability exist, though this may be difficult for various reasons. Simchi-Levi et al. (2012) point to the floods in Thailand and the tsunami in Japan as examples of natural disasters in the Asia-Pacific region that affected companies' supply chains.

4. Cost Implications at the New Location(s)

Linking with the cost and time benefits discussed in the Chapter 3.1, when evaluating what products could be manufactured successfully in the Asia-Pacific region, various costs must be evaluated for each location. Moreover, potential changes to and uncertainties around these costs

should be taken into account. The following is a list of location-specific costs and uncertainties that should be accounted for in choosing the appropriate locations in addition to being part of the decision analysis:

- Capital Project Costs & Timelines
- Country-Specific Price Inflation
- Labor Costs & Wage Inflation
- Transportation Costs at the New Location (while it is dependent on the transportation mode and routes for the chosen location, freight inflation will also affect this cost; further details are discussed in Chapter 3.3)
- Changes to Foreign Exchange Rate(s) Over Time
- Import Duties & Taxes as a Result of Operating in the New Location (also evaluate potential changes of meeting free trade agreements)
- Income Tax Strategy at the New Location

Governments may offer incentives to attract companies and industries. For instance, if a company qualifies for Pioneer Status in Malaysia, it is exempt from paying duties on imported raw materials if the products are manufactured for export markets (Ernst & Young, 2012, p. 7). In addition, certain costs and uncertainties (e.g., capital project costs and transportation costs) are dependent on how the supply chain is structured, and the next section discusses the impact of those decisions.

The criteria above should serve as a guideline, since every medical device manufacturer will have a different perspective on the importance of each factor. In addition, it is not necessary to evaluate every location in the Asia-Pacific region. For the Supply Chain Group, its desire to establish a campus approach tends to narrow the focus on certain locations versus a traditional "greenfield" approach (i.e., a new site in a new location).

3.3 Decision Criteria for How to Conduct Manufacturing Operations

After the products for regional sourcing are identified, the next step is to determine how supply chain should be developed or modified and what modifications, if any, are required. Since every manufacturer will have a different approach for developing their supply chains as part of the footprint strategy, this section mainly provides an overview of the considerations that the Supply Chain Group has and will face when using the methodology. Figure 8 shows the major considerations for this part of the analysis (original figure from Christodoulou et al., 2007, p. 10):

- Considerations for Outsourcing Manufacturing Operations
  - IP Sensitivity
  - Predictable Demand
  - Low Profit Margins
  - High Opportunity Cost
- Value Chain Analysis
  - Firm Infrastructure & HR Management
  - Procurement & Inbound Logistics
  - Operations & Technology Development
  - Outbound Logistics

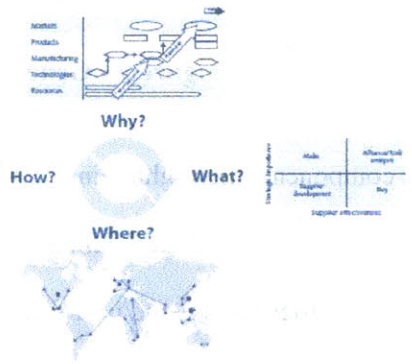


Figure 8 - Decision Criteria for the "How" Analysis

The value chain analysis provides a structured way for medical device manufacturers to successfully develop or modify their supply chains in the Asia-Pacific region while also accounting for the various functional considerations (e.g., current procurement strategy, current transportation methods, technology transfer experience). Porter (1985) presents a high-level overview of the value chain in Figure 9 below (note: the model has been modified for the methodology):

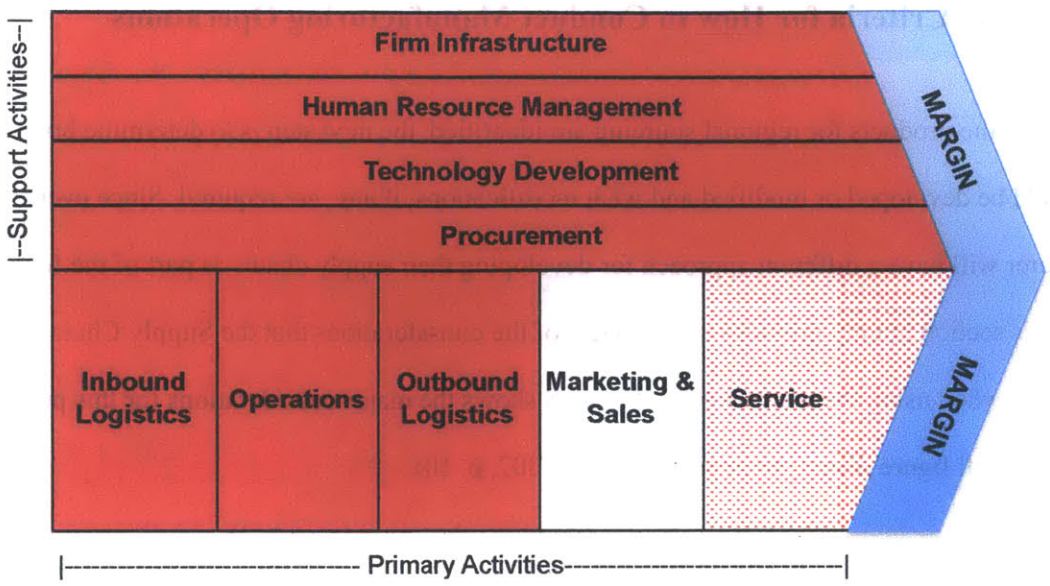


Figure 9 - Generic Value Chain by Michael Porter

Each of the components highlighted in red must be evaluated in order to decide what modifications to the supply chain will be required. In the medical device industry, Service (semi-highlighted) is primarily tied to the education, order taking, and user feedback for the devices. This is typically handled by the commercial organizations for each subsidiary rather than Supply Chain Group at Company X and at other medical device manufacturers. Companies that involve service operations as part of their supply chain, however, will need to evaluate that component as well.

Before any part is individually evaluated, it is worthwhile to determine whether the entire manufacturing process could be outsourced in the Asia-Pacific region, thus reducing the complexity of a supply chain that relies on internal manufacturing. The decision for whether to outsource manufacturing operations is made as part of a Make-or-Buy Analysis, and every manufacturer will have varying criteria for this analysis. All pipeline products for Division A generally go through the Make-or-Buy Analysis prior to making any decisions affecting internal manufacturing. The current Make-or-Buy Analysis, as conducted by the Supply Chain Group, accounts for the following: process design / technology, supplier quality, infrastructure requirements, impact to supply chain, and financials for both the third-party

supplier and Company X. Once the initial decision is made, it is arbitrary as to whether products are re-evaluated as potential outsourcing candidates. The following criteria, formed in conjunction with the Supply Chain Group, that can be used to determine whether manufacturing for the identified products can or should be outsourced:

1. No IP-Sensitive Information / Not Considered a Core Competency

   If the technology used in the device manufacturing process is not considered part of a company's core competency and there are no major threats to IP rights, outsourcing production should be considered. This is especially important if there are contract manufacturers who have good reputations for making those products while also meeting regulatory requirements.

2. Predictable Demand Forecasts

   One of the difficulties with products in the early stages of their lifecycles is forecasting demand accurately. However, if demand is relatively predictable and the forecast accuracy is high, working with contract manufacturers should be easier since there will be less flexibility requirements. Company X uses the mean absolute percent error (MAPE) as a way of determining forecast accuracy. A low MAPE value is an indicator of a higher forecast accuracy.

3. Low Profit Margins

   If profit margins are low, it may be feasible to find a contract manufacturer who can make the product at a lower cost while also maintaining the same quality standards. For the Supply Chain Group, the cost assessment is done as part of the Make-or-Buy Analysis. In addition, processes used to manufacture devices with higher profit margins tend to require significant IP protection at Company X.

4. High Opportunity Costs Compared to Other Products

In a situation where manufacturing space becomes a consideration, there could be trade-offs with manufacturing one product versus another. For example, the Supply Chain Group is dealing with a space issue at one of its existing facilities. In order to support production of pipeline products, they are considering outsourcing production of products with lower production line utilization rates and that take up a significant amount of manufacturing space in an effort to create the required space. In this way, it could still meet customer demand while also supporting product of newer, more innovative devices.

As mentioned before, early-stage devices that are identified as regional sourcing candidates are already evaluated through a Make-or-Buy Analysis at Company X. However, if a product that is already produced commercially meets the criteria listed above, the Make-or-Buy Analysis should be applied again.

Analyzing each of the components in the supply chain is an arduous task, and every medical device company will likely have a different idea about what to investigate in developing a supply chain for each of the evaluated products and locations. Through my research with Company X, a number of considerations were discovered that would effect how the supply chains of all of its medical devices would be developed. Although these considerations are company-specific, other medical device manufacturers may face similar considerations when using the methodology. These factors, which are grouped by their respective value chain components, are as follows:

1. Procurement & Inbound Logistics

When developing a manufacturing footprint strategy or making footprint decisions, there is an opportunity to modify the procurement strategy of an existing product line or create a new overall strategy. For example, local raw material suppliers could be validated and utilized in order to increase manufacturing flexibility and decrease material lead times. In addition, there could be

cost reduction opportunities when identifying new suppliers, but these must be reviewed in conjunction with supplier performance. The External Operations Group would prefer to use the suppliers that it already has established relationships with. This avoids the need for of identifying and qualifying new suppliers, which can be very costly and time-consuming. One senior leader at Company X believes that technologies such as injection molding and metal forming in the Asia-Pacific region are not up to the medical-grade standards that Company X would require for its suppliers. It would be ideal if the current suppliers had existing facilities in the region or would be willing to expand there if the Supply Chain Group were to increase its presence there. However, one procurement leader noted that it was not the main criterion for future success. Company X has had experience with suppliers establishing a manufacturing location near the new locations and not being able to deliver quality raw materials in a timely manner. If the suppliers do not have regional locations or will not be able to establish one, the Supply Chain Group is willing to pay to ship materials from their current locations to the new location, as long as the potential costs (transportation, duties, etc.) and freight inflation are not significant in comparison to the actual material costs.

2. Operations & Technology Development

The Supply Chain Group is generally conservative when it comes to transferring and modifying unit operations or processes as part of its footprint strategy development. Although changes can be made as part of the technology transfer process, the group tries not to make significant changes due to the impact that the changes would have on product registrations and the ability to sell devices in various markets. Also, if there are IP concerns with the technology transfer (e.g., processes with trade secrets), steps could be taken to withhold or alter those processes in order to protect the IP. Further discussion on the topic of manufacturing intellectual property rights can be found in Chapter 5. On the other hand, the Supply Chain Group is not opposed to outsourcing certain operations that are not IP-sensitive and are not considered competencies. The Supply

Chain Division at Company X conducted a process technology audit across all manufacturing sectors over the past two years to identify its manufacturing core competencies (i.e., what technologies were the most critical to their internal operations) and to determine what processes could potentially be outsourced. As an example, the sterilization operations for Product Line B could be outsourced since it is not considered a core competency (specific details can be found in Chapter 6). Once the unit operations and processes are decided upon, the next step is to determine what capacity is required. Although this may be dictated by the capacity needs (i.e., determined as part of the "What" phase), there is an opportunity to include equipment and processes for further product line growth or even for other product lines. On the other hand, it may be more worthwhile to initially build the infrastructure and purchase equipment at a later date when the capacity needs are better defined (as highlighted in Point 1).

3. Outbound Logistics

Outbound logistics (i.e., the type of freight used and the route) will have an impact on the supply chain development, specifically on the lead times and the total operational costs. Company X currently transports many of its medical devices by air freight to the distribution center(s) in the region. While this leads to a significant reduction in lead times, it could be a significant cost burden for most other medical device manufacturers. The Transportation Group, which is part of the Supply Chain Group, would need to evaluate the freight type on a case-by-case basis if a new location were to be established as part of the footprint strategy. With respect to the implications of route preferences on Outbound Logistics, all of Company X's products sold in the region will ship from the distribution center in Singapore to local warehouses in the countries where the transaction(s) takes place (this is discussed further in Chapter 2.2). This has significant implications in developing the supply chain for Product Line B as part of the case study in Chapter 6. For example, when evaluating the Malaysia option, finished goods could be shipped by truck from Malaysia to the distribution center in Singapore. This would be a significant cost

advantage in comparison to the China and India options, both of which would require air transportation to the same distribution center.

4. Firm Infrastructure & Human Resource Management

The decision to expand at an existing campus or in an existing building, in addition to planning for capacity expansion, impacts the company's decisions around firm infrastructure and human resource management. As mentioned before, stakeholders at Company X are primarily interested in employing a campus approach when considering manufacturing footprint expansion as opposed to building a single manufacturing facility in a new location. Employing a campus approach will likely reduce the overall project costs, help develop staff capabilities around the existing campus, and reduce operating expenses. However, the Supply Chain Group is not opposed to considering a "greenfield" project if there are potential cost advantages that are not available at its existing locations. In addition, an existing facility in a campus location could have unused space that can be retrofitted for a new product line. This will lower the project construction costs, since a new building is not required, and it will allow current employees to develop competencies in new unit operations. The Supply Chain Group has a Site Selection Process that helps them in identifying current sites in the network that could handle additional capacities as needed, but a majority of the existing sites are not in the Asia-Pacific region. Once the location(s) have been decided, the next step is to determine the current and future capacity needs. This is a decision that the subsidiaries at Company X have had trouble with when they managed their individual supply chain operations. On one hand, the project costs will be lower with a "bare minimum" approach. However, building the infrastructure for future expansion early on will reduce the costs and timelines in the future. The expansion decision must also be coordinated with the scale of unit operations to be implemented initially as discussed in Point 3.

Once the "What", "Where", and "How" decisions have been made, the next step is to evaluate the various options to determine the best path forward. This evaluation involves decision analysis, and all potential risk factors must be considered.

3.4 Decision Analysis & Accounting for the Risk Factors

When making decisions regarding the manufacturing footprint strategy, all risk factors must be accounted for as part of the decision analysis. Table 1 below includes a list of the risk factors and uncertainties, broken down by the phase in which they are most applicable, to account for as part of the decision analysis (note: these are also discussed in the previous sections of this chapter):

Table 1 - Summary of the Risk Factors & Uncertainties to Evaluate as Part of the Decision Analysis

Methodology Phase	Risk Factors & Uncertainties
"What"	• Variations in the Sales & Demand Volume Forecasts • Effect of a Supply Disruption
"Where"	• Capital Project Costs & Timelines (location-specific) • Wage Inflation • Country-Specific Price Inflation • Long-term Changes to Foreign Exchange Rates • Changes to Import Duties & Taxes
"How"	• Capital Project Costs & Timelines (operations-specific) • Changes to Material Costs • Freight Inflation (combination of price changes to fuel & freight)

Since there are many uncertainties and risks to observe, the most effective way to account for them is to develop three distinct scenarios – optimistic (best-case), realistic, and pessimistic (worst-case) – for which the decision analysis tools can be applied. The uncertainties and risk factors are considered to be more favorable in the optimistic case and vice-versa for the pessimistic case. Appendix A illustrates how these risks factors and uncertainties were accounted for in the case study for Product Line B, and Table 11 in

the appendix lists the values that were applied. These values were determined through a combination of economic outlooks, industry research, and input from key experts across Company X.

Three decision analysis tools can be used to determine the best way forward with regards to footprint strategy. Each of the tools selected provides certain information that the other tools do not, and using them in combination can provide a complete picture. The following tools, along with the reasoning for their respective selections, were used for the evaluation in Chapter 6:

1. Total Landed Cost Analysis

   Calculating the total landed costs can help to determine which of the locations chosen will be able to supply the Asia-Pacific region at the lowest cost, and they can be compared against the total landed costs for the current source. For Company X, the total landed cost analysis includes specific costs that are generally accounted for in the NPV analysis conducted by the Finance Group, thus providing a way to determine the impact of those elements. Simchi-Levi et al. (2008) give an overview of the components that should be accounted for in a landed cost analysis (p. 288). The analysis should be conducted for each of the three scenarios to determine the variation in landed cost.

2. Net Present Value (NPV) Analysis

   Simply put, this is used to determine the value of a potential investment for each scenario. The total landed cost analysis does not fully account for the initial investment requirements for each project, and an option that has a lower total landed cost over the scenarios analyzed may not be the most prudent investment when accounting for the capital project costs. Moreover, the results of the NPV analysis for each of the three scenarios are needed for the decision tree analysis as discussed in Point 3. Medical device companies will have slight variations on how the NPV is calculated based on their preferences. At Company X, the Finance Group is working towards

standardizing the way that the NPV analyses are conducted across the entire organization. The NPV analysis conducted in this evaluation was completed with the company's existing model, and specific model details cannot be provided in order to protect proprietary information. Similar to the total landed cost analysis, the NPV should be calculated for each of the three scenarios to determine the variation between the values.

3. Decision Tree Analysis

A decision tree can be used to determine the best decision to make under scenarios that take into consideration various uncertainties and risks. As part of the manufacturing footprint strategy development for Company X, this analysis can be used to determine if it would be worthwhile to expand manufacturing operations in a new regional location or continue manufacturing in an existing location. In situations where the total landed cost and NPV analyses tend to favor a single sourcing option (e.g., due to an existing location with sunk costs or perhaps because of the investment requirements), a decision tree analysis can account for the possibility of a plant-wide failure to determine whether it is more valuable to use a single or dual sourcing strategy. For this analysis, the NPV values for all three scenarios are required inputs for the decision tree analysis.

The overall results for the analysis conducted with Company X are given in Chapter 6, and further details can also be found in Appendices A and B. The original data for the total landed cost and NPV analyses presented in Chapter 6 and Appendix B was modified to protect confidential information for Company X.

It is also worthwhile to conduct some type of sensitivity analysis to determine how the outcome will change as the uncertainties change. The results from the sensitivity analysis can be used as "trigger points" to determine when a new plan of action is needed. Chapter 6 also includes the results from the sensitivity analysis performed that can aid in determining what factors have the greatest influence on the decision.

4 A Business Process for Making Footprint Strategy Decisions

There are a number of ways that the methodology described in Chapter 3 can be applied in order to make footprint strategy decisions. Company X is concerned with who should be involved, what data should be reviewed, and how often should a review be completed. Experts at the Institute for Manufacturing at the University of Cambridge believe that the business process "needs to be fully integrated into the business planning cycle and needs to be the definitive basis for all manufacturing network decisions" (Christodoulou et al., 2007, p 40). This chapter explores a business process for making manufacturing footprint strategy decisions and outlines a process designed for Company X.

4.1 Roles & Responsibilities

The objective for each team member is to develop and share the information required per the outlined methodology, and the team must develop consensus around the shared results. In developing an Asia-Pacific manufacturing footprint strategy, input from the following groups is needed as part of the business process:

- Manufacturing Operations & Strategy
- Engineering
- Quality & Regulatory Affairs
- Commercial Operations (i.e., sales & marketing)
- Research & Development
- Production / Demand Planning
- Procurement & Strategic Sourcing
- Logistics (i.e., transportation, distribution)
- Finance

- Human Resources (HR)

Although having enough representation from various groups is required in order to gather data quickly and make an informed decision, having too many people involved can make it difficult to build consensus within a suitable timeframe. Certain individuals can provide input from multiple groups based on their role in the company and/or previous experience. In addition, there should be a designated leader to coordinate responsibilities as part of the business process.

Six roles were identified as being crucial to the business process at Company X, and one person should represent each group. Table 2 shows the members of the primary team and their roles in the business process, including what information they are responsible for (note: team members from the Subsidiary Operations Development and Finance Groups are not directly part of the Supply Chain Division even though they work closely with the division in general):

Table 2 - Roles and Responsibilities for Each Member of the Business Process at Company X

Group Represented	Business Process Role & Responsibilities	Primary Methodology Inputs ("What", "Where", "How")
Supply Chain Strategy	• Team lead • Responsible for providing input from the following groups as part of the process: HR, Legal Affairs, and Transportation • Coordinates with Manufacturing and Finance on their required deliverables as described in their respective sections	• Coordinating with HR: Talent Availability, Language & Cultural Barriers, Political & Environmental Stability, and Human Resource Management • Coordinating with Legal Affairs: IP issues • Coordinating with Transportation: Requirements for Inbound and Outbound Logistics, Associated Cost Implications and Potential Benefits (e.g., decreased lead times, cost savings) • Decision Analysis and Risk Factors
Subsidiary Operations Development	• Represents the Commercial and R&D Groups as part of the business process • Provides data for the expected sales forecasts • Coordinates with all other team	• Regional and Global Demand • Process Complexity (e.g., regulatory classification, process maturity, IP issues, operating capabilities required, investment required) • Requirements for Firm Infrastructure

	members to provide support as needed based on his/her in-depth product operations experience	and Operations/Technology Development
Manufacturing	• Provides demand volume forecasts and capacity utilization • Coordinates with External Operations on procurement requirements	• Current Network Capacity (and future needs) • Coordinating with External Operations: Procurement Requirements, Supplier Availability, and Proximity to Suppliers • Requirements for Firm Infrastructure and Operations/Technology Development
Manufacturing Engineering	• Provides input for capital project requirements, manufacturing process technologies, and validation requirements	• Investment Required (e.g., capital project costs) • Operating Capabilities and IP Requirements (e.g., core competency determination) • Technology Availability (by location) • Requirements for Firm Infrastructure and Operations/Technology Development
Quality	• Provides input on quality considerations for the processes being evaluated (e.g., process maturity, quality requirements for raw material & finished goods) • Provides input for regulatory and product registration requirements for each potential location	• Process Complexity (e.g., regulatory classification, process maturity, IP issues, operating capabilities required, investment required) • Ability to Meet Government and Regulatory Requirements • Requirements for Firm Infrastructure and Operations/Technology Development
Finance	• Provides financial input to the team (e.g., cost accounting, tax strategy, economic risk factors) • Coordinates with Supply Chain Strategy on completing the decision analyses	• Operating Costs (current and future) • Investment Required • Decision Analysis and Risk Factors

The Supply Chain Strategy Group, which is a separate group within Company X's Supply Chain Division, includes members who work specifically in the medical device sector. The personnel in the group are the most suited to lead the business process due to their previous experience with

manufacturing strategy projects and existing relationships with supporting groups. If additional people are required to provide input as part of the process, the team can be expanded. However, the group size should not grow beyond ten persons in an effort to efficiently build consensus. The initial team will run through the methodology criteria described in Chapter 3 and evaluate the decided-upon possibilities as part of the decision analyses. Although each role has specific inputs that they are responsible for, these can be shifted if certain members are better suited for providing the required inputs (e.g., a member from the Subsidiary Operations Development Group could provide the required procurement information if he or she has previous experience in this field). It is up to the team leader to decide. The team will report the results and any required information to the leadership team for the Supply Chain Group.

The Supply Chain Strategy Group will also be responsible for analyzing the updated information periodically as part of the business process. If any changes occur that require changes to the manufacturing footprint for the product lines identified, the person responsible should contact the Subsidiary Operations Development Group to verify these changes and discuss next steps. Both parties work closely together in the project formation and execution phases at Company X currently. If a formal project is required, the responsible person(s) will approach the senior leadership team in order to initiate a capital approval request.

4.2 Frequency of the Review Process

The timeliness of the decision-making process is another key concern. Christodoulou et al. (2007) found that the decision-making for a manufacturing footprint strategy is usually completed on an ad-hoc and infrequent basis, and it is usually done in response to profit loss or increased competition. The information gained from the initial analysis should be reviewed frequently to keep track of any changes that may happen. For Company X, the information should be reviewed quarterly or semi-annually, depending on how often the revised data is available. This will allow enough time for the Supply Chain

Group to proactively react to potential changes instead of finding out about them after the fact. For example, Company X may not be able to react quickly enough to a major regulatory change (e.g., implementation of Pharma 2020 in Russia) if the data were only reviewed annually. If any changes are identified that warrant modifications to the manufacturing network as decided by the team (e.g., significant increases to the sales forecast or major changes to import duties), the Supply Chain Strategy should work together with other supporting groups (e.g., Subsidiary Operations Development, Finance) to evaluate the project using the current project assessment tools available. Furthermore, the leadership team of the Supply Chain Group can prioritize potential projects as part of annual planning cycle or sooner if required.

The Supply Chain Group has already developed a Network Strategy Toolkit, which includes actionable steps taken during a project's development, deployment, and implementation. The existing toolkit does not follow a rigorous process for using the decision analysis tools, and both the team formation and the analysis is done on a case-by-case basis. The business process presented in this chapter provides a structured way for manufacturers to organize and manage the process, and these elements should be integrated into the toolkit developed by the group.

5 Intellectual Property Considerations for Footprint Strategy Decisions

When developing a manufacturing footprint strategy, intellectual property (IP) rights must be considered when evaluating a potential manufacturing location. One of the most concerning issues when considering manufacturing footprint strategy development for the Asia-Pacific region is trade secret protection. Although most countries in the region have laws to protect IP rights, certain countries, such as China, are still known for counterfeiting and their lack of IP protection (Bai and Da, 2011). While other forms of protection, such as patents and copyrights, are legally protected for a finite amount of time, trade secrets are only protected as long as they are safeguarded. Thus, if a trade secret is revealed to a competitor in any way, it can be very difficult to make up for the financial loss and brand damage.

In this section, the properties of a trade secret are explained, and an example is provided to demonstrate how the properties can be applied to the Process Technology A at Company X. In addition, the ways to protect trade secrets are described in further detail. The investigation conducted has led to an overall understanding that manufacturing processes that involve trade secrets should generally be located in countries with strong reputations for IP protection.

5.1 Trade Secret Definition & Requirements

Many sources define what a trade secret is and what constitutes a trade secret. One of the most widely accepted definitions of a trade secret comes from the Unified Trade Secrets Act, which defines a trade secret as "information, including a formula, pattern, compilation, program, device, method, technique, or process, that (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy" (National Conference of Commissioners on Uniform State Laws,

1985). Examples of famous trade secrets include the recipe for Coca-Cola® and the formula for WD-40®.

In order for a process to be considered a trade secret, Jorda (2007) and Dratler (1991) argue that the following criteria must be met:

1. The process gives the manufacturer a competitive advantage over the competition

   The process provides either a cost advantage or a product characteristic advantage. For example, a manufacturing process that allows a company to minimize its operating costs will give it a competitive advantage and could be considered a trade secret.

2. The process itself is kept a secret

   Pertinent information is safeguarded from the public and personnel that are not involved in the operations. Protection can include keeping documents under lock-and-key or having password protection with digital documents. In certain cases, certain setup or operating steps may only be known by certain individuals to mitigate the release of proprietary information.

3. The process is not generally known or used by competitors (i.e., not common knowledge)

   If a process is well known among competitors, it cannot be considered a trade secret. However, it is possible for a trade secret to be known and used by other competitors, as long as they developed the processes independently (Jorda, 2007).

If a manufacturer were to file a lawsuit against another party for trade secret misappropriation, this criterion would need to be satisfied in the eyes of the court. Assuming that all three points are met, manufacturers must then decide what steps to take in order to protect it.

5.2 Trade Secret Protection Methods

Based on the research conducted, there are three ways that a company can protect its trade secrets when looking to expand its manufacturing footprint:

1. Ensure that it is illegal for employees with process knowledge to reveal proprietary information and reminding those individuals of their legal obligations
2. Utilize other IP protection methods in combination with trade secret protection
3. Use a different process to produce a component or device in order to protect the original trade secret process

Company X currently employs the first and second ways to protect its devices that are currently available. Both the Supply Chain Group and product experts in each of the subsidiaries manage IP protection for the range of devices. The benefits and risks of each way are examined in the upcoming sections.

5.2.1 Applying Current Legal Methods to Ensure Protection

There are many ways to protect a trade secret from the outset. One of the most common ways is to have individuals who are potentially exposed to such proprietary information sign a number of confidentiality agreements, including but not limited to the following agreements: non-disclosure, IP assignment, and non-compete. Jorda (2007) suggests other ways to protect proprietary information, such as conducting regular training and exit interviews for people exposed to proprietary information in order to remind them of their obligations. In addition, manufacturers should continue to protect information relating to process trade secrets by any means possible so as to avoid the information from falling into the wrong hands.

While these methods are certainly applicable, there is still the risk of an employee breaking the law and revealing the trade secret(s) to other companies or using them for personal gain. China and India both received poor rankings for intellectual property protection in a 2012 survey conducted by the Global Intellectual Property Center of the U.S. Chamber of Commerce, signaling weak IP protection in both countries; in fact, both countries received the lowest scores for trade secret protection (Global Intellectual Property Center, 2012). Manufacturers should keep this in mind when developing their footprint strategies.

5.2.2 Combining IP Protection Methods to Protect a Trade Secret

In addition to adhering to the traditional methods of protecting a trade secret, further protection can be done by utilizing other forms for protection, such as patent protection, copyrights, and trademarks. For example, Dratler (1991) recommends copyrighting the instructions for a specific process so that competitors cannot use the exact same document. Another example, which is currently employed by Company X and many of its competitors, is to patent parts of the product design. The respective subsidiary in Company X has several patents for Product Line B that include information specific to the design of the instrument and the consumable component.

Although patents and copyrights serve as additional steps for protection in these circumstances, there is no legal protection on the design or instructions once the patents or the copyrights expire. Competitors are free to copy and sell the products at will. In a similar light, medical manufacturers should be very careful when patenting a manufacturing process outright; competitors are allowed to use the process once the patent has expired. Moreover, certain competitors will not be dissuaded by additional IP protection in the Asia-Pacific region as evidenced by Bai and Da (2011).

5.2.3 Using a New Process to Manufacture the Intended Product

The most effective way to protect a process containing a trade secret is to change the process in such a way that the trade secret is not applied outright (i.e., reinvent or modify the process). Such a change would require significant process development expertise and time in order to execute. Furthermore, there is a high probability that the new process will be less efficient than the trade secret process, so this should be considered when evaluating the required manufacturing output at a facility. This scenario should only be considered if a medical device manufacturer is willing to sacrifice an operational advantage in order to gain or increase market access (e.g., the requirement to manufacture 50% of products domestically in Russia).

While this may be enticing for companies that must produce in a location that does not maintain adequate IP protection, there are significant risks. First, if the product manufactured is intended for export to other countries, changes to the product registration will be required in order to distribute products that are manufactured using the new process. The product registration process requires manufacturing process validation for the products and components sold in that country. Second, since a new process is being used to make the same product, the government health agency in the country where re-registration is occurring could require additional steps to verify that the product manufactured through the new process performs to the same expectations to those manufactured in the old, trade secret process. This could require additional clinical trials, directly adding additional costs and lengthening the time requirements for product registration. Based on these risks, process modifications should only be made in extreme circumstances. Two examples include the following: if the products manufactured using the modified process will only be sold in a country requiring the new process, or if the manufacturer believes that costs for the changes to product registration and the required trials are not significant compared to the potential revenue gain.

5.3 A Case Study with Process Technology A

Product Line B, which was evaluated as part of the case study in Chapter 6, includes two components needed to perform its intended use during a procedure – an instrument and a consumable component. The revenue from the consumable component made up nearly 65% of revenues for Product Line B in 2011. Company X has developed a robust process technology (Process Technology A) to assemble these components at a rapid pace and with minimal operator intervention. The process efficiency has allowed the franchise to significantly minimize production costs, and the consumable components have higher profit margins than the instruments themselves. If competitors were able to produce the same components, Company X would lose significant market share and revenue. Moreover, there could be product safety issues if the competitors did not produce them to the same quality standards. In many ways, the associated recalls could be more detrimental to Company X than the actual revenue loss.

There has been some debate at Company X as to whether Process Technology A should be considered a trade secret. Based on the criteria defined in Chapter 5.1 the process should be considered a trade secret as described in Table 3 below (Jorda, 2007; Dratler, 2001):

Table 3 - Evaluation of Process Technology A as a Trade Secret

Trade Secret Criteria	Reasoning for Process Technology A
Process Provides a Competitive Advantage	• Process Technology A allows for to mass-production the assembled consumable components with minimal operator intervention (i.e., low-cost operation).
Process is Kept Secret	• Machine and process drawings for the process are password-protected. • The setup procedures are only known by certain Maintenance & Engineering staff, and extensive training is required
Process is Not Common Knowledge	• A minimal number of competitors make the consumable components comparable to those for Product Line B. • Counterfeit components have not been found in distribution channels (note: counterfeit instruments have been found though) according to Company X.

The Supply Chain Group has taken a number of precautionary steps to protect Process Technology A. Employees at the facilities where the technology exists must sign a non-disclosure agreement that includes a non-compete clause. Exit interviews do generally take place to remind employees of their legal obligations after they have left the company. As mentioned in Chapter 5.2.2, the group has also patented its component design in conjunction with patents pertaining to the instruments. Therefore, if a competitor or a counterfeiter were able to use the same process, they would need to design a new consumable component that could be used by the same instrument. This, in itself, is a daunting task with no guaranteed success.

Certain personnel who are familiar with Process Technology A have found a potential way to modify the process in such a way as to protect the proprietary knowledge of the original process. The change involves loading the components into the machine so that certain elements of the original machine design would not be needed in the new process. While further development is required, there are immediate issues with this change. First, it will take an immense amount of time and resources to develop and implement the new process. In addition, assuming that the modified process is not as robust as the original process, a greater investment would be required in order to match the expected output that the original process could deliver. Second, there would be modifications to current product registrations, and new clinical trials may be required in order to sell the new components. These are major hurdles for the Supply Chain Group, so much so that certain Group leaders are willing to locate the process as is in countries such as India and China rather than modify the process for further protection.

5.4 Valuing the Loss of a Trade Secret

As mentioned before, Company X is hesitant to place certain process technologies in places such as China and India for fear of trade secret misappropriation. In addition to the loss of the trade secret itself, the company would have to prove in the respective courts that trade secret misappropriation

actually took place. This can be challenging in situations where Company X had limited legal experience in a certain country or if that country does not have stringent laws around intellectual property. Bai and Da (2011) review a variety of trade secret misappropriation cases that took place in China. Although trade secret enforcement is possible, the burden of evidence is higher for the plaintiff (i.e., the group or company that lost the trade secret) compared to what is required in the United States (Bai and Da, 2011).

A process technology can be used to produce either a competitive product (i.e., the competitor is not found guilty of trade secret misappropriation and competes directly with the existing producer) or a counterfeit product that appears and functions like the original product. Groups or companies making counterfeit products will not have to pay the marketing costs associated with a competitive product, since they are attempting to penetrate the current manufacturer's supply chain rather than compete against them. However, since their product is a counterfeit, they could be subjected to further violations of intellectual property rights beyond trade secret misappropriation (e.g., copyright and trademark laws). For Product Line B, Company X has found counterfeit versions of the instruments, but it has not found counterfeit versions of the consumable components in the Asia-Pacific region. Since very few companies make competitive products with Product Line B, Company X believes that those who are able to ascertain information about Process Technology A will be able to produce the consumable components and make either counterfeit or competitive products.

The true value of a trade secret loss will depend on the product (competitive or counterfeit) and the circumstances. For instance, the costs and customer acceptance rates would be different in the situation where the trade secret were used to manufacture counterfeit products compared to a situation where the trade secret was used to manufacture a competitive product. Through the research conducted with Company X, a generic equation to determine the economic value of a trade secret if it were revealed was determined as follows:

$$Trade\ Secret\ Value$$

$$= (Global\ Net\ Profit \times Global\ Market\ Penetration \times Customer\ Acceptance) + Remedy\ Costs$$

Global Net Profit represents the total net profit that is tied to the process technology. The global net profit tied to Process Technology A, which is an essential process step in making the consumable component, is more than three quarters of the global net profit for Product Line B. Company X conservatively assumes the highest value for Global Net Profit that accounts for all of the product lines utilizing the trade secret process. However, the competitor or counterfeiter may not understand the full implications of the trade secret and, therefore, not maximize the economic value (e.g., competitors not producing other products that utilize the trade secret).

Global Market Penetration represents the percentage of the market that is affected by the trade secret misappropriation. For counterfeit products, global market penetration will be higher if those products are found in multiple regions worldwide. The Supply Chain Strategy Group assumes a 100% market penetration value in those situations. Company X also reported that it has found competitive and counterfeit products that were only sold in a few specific countries are not found to be circulating in its international supply chain. The market penetration would be lower in those situations since only a certain location or region is affected.

Customer Acceptance represents the probability that customers will buy and use the other product over the other product. If it is a counterfeit product that the customer purchases unknowingly, the probability of customer acceptance is typically low. Company X has extensive procedures for what customers should do if they have been unknowingly sold a counterfeit product. On the other hand, if the new product is considered to be a competitive product, the customer acceptance value could be higher. For Product Line B, Customer Acceptance will be higher if the competitor is able to sell the consumable components at a much lower cost, assuming that it is a competitive product. However, it will likely not reach 100% due to brand loyalty by customers or the competitive discounts that Company X would need to offer.

Remedy Costs represent the costs required for these will be different under each circumstance. For example, if counterfeit products were manufactured using the trade secret and it is deemed as a trade secret misappropriation, the costs will include all associated legal fees and costs for product recalls needed in order to determine the impact the supply chain. While the total cost of the recall will vary by the situation and the industry, companies estimate the recall costs to be $30M or less (Ernst & Young, 2011). However, the costs could increase significantly if patients are harmed through the use of a counterfeit product. If the trade secret is lost but the court does not rule it as trade secret misappropriation, the costs will include the additional marketing costs needed to stay competitive as well as the associated legal fees. In addition, the company will likely have to reduce its prices to stay competitive in the affected markets.

There are limitations with the equation that will also vary on a case-by-case basis. First, these costs do not reflect the potential damage to a company's brand reputation, especially if a product recall is required in the case of counterfeit products (Ernst & Young, 2011). Second, the values for Global Net Profit, Market Penetration, and Customer Acceptance could change over time if the competitor is not guilty of trade secret misappropriation and is able to successfully compete in the market. Company X is trying to gain a better understanding of these changes with its Asia-Pacific competitors. In this case, the equation still provides a starting point for the total economic loss due to trade secret misappropriation.

5.5 A Potential Path Forward with IP Protection in the Asia-Pacific Region

While the relevant IP protection mechanisms are in place, there may be competitors who will still ignore the legal implications and attempt to copy these devices or processes. If the Supply Chain Group were to locate manufacturing for Product Line B in places such as China or India, it would be taking a risk by including Process Technology A as part of the process operations. On the other hand, the Global Intellectual Property Center Report commented that Malaysia, which is also evaluated as a potential

location in Chapter 6, has "reasonable trade secret protection" due to key rulings in recent court cases (Global Intellectual Property Center, 2011, p. 60). It may be possible to only manufacture the instruments at the new facility but then they would need to continue shipping the consumable components from the current facility in North America. A certain number of these components would also need to be shipped to the new regional manufacturing location in order to test the instrument as part of the manufacturing process. The Supply Chain Group would prefer to have the instrument and component manufacturing processes in the same location.

Given the risk of counterfeiting in the region and the risks of implementing a new process to make the same product, it is advisable to locate manufacturing processes with trade secrets in locations with strong reputations for IP protection. Examples in the Asia-Pacific region that are known to have such a reputation include Japan, Singapore, and Australia. However, these locations are also known to having higher operating costs, so the potential savings may not be as great when compared to manufacturing in the U.S. or Western Europe. For the purposes of the case study in Chapter 6, it was assumed that IP protection for Process Technology A could be established in all three with no process modifications required. In reality, this decision would need to be reviewed further by the business process team as outlined in Chapter 4.

6 Application of the Methodology at Company X

This chapter presents a case study using the broadly applicable methodology that I developed as part of my research with Company X. The methodology is applied to a subsidiary within the company that develops and markets a variety of medical devices. This subsidiary was initially chosen for its Asia-Pacific growth opportunities over the next seven years and the fact that the product lines are currently single-sourced (i.e., only one manufacturing location).

The decision analysis tools were applied to three specific regional options, and each location had a different manufacturing setup with different space constraints, project costs, and operating costs. The Malaysia option is a "greenfield" project; the China option includes a new manufacturing facility on an existing campus; and the India option is a retrofit of a vacant and available space within an existing facility. These options were compared to the current source in North America. At the time of writing, no engineering modifications (e.g., a facility expansion or additional assembly equipment) would be required to meet the expected future demand in North America till 2019. Additional labor shifts, although costly, could be added to meet demand if the circumstances required such action. Thus, the decision analysis needed to show that the benefits derived from expanding in any of the Asia-Pacific locations chosen outweigh the costs in the existing North American location, where the infrastructure already exists (i.e., there are sunk costs). In this case study, we find that those benefits do not justify expanding in the Asia-Pacific region. However, project leaders in the Supply Chain Strategy Group acknowledge that there may be situations with other subsidiaries in which the regional expansion benefits outweigh the expected costs.

Although the methodology was applied to a subsidiary with existing product lines and with some existing capacity, it is also applicable for product lines that are not currently being manufactured since the user would follow the same steps in order to determine the best course of action with regards to expansion decisions (e.g., deciding whether it is better to build a new facility at an Asia-Pacific location or to build commercial manufacturing capabilities in another location). This situation is discussed in more detail in Chapter 7.1. The data presented in this chapter has been modified to maintain the confidentiality of

Company X's proprietary information where it was deemed appropriate. Appendices A and B include detailed information regarding the analysis.

6.1 Evaluating What Products are Suitable for Regional Sourcing

Chapter 3.1 outlines the criteria needed to determine what products make sense for regional sourcing for the chosen subsidiary. This subsidiary accounted for nearly 8% of Company X's total revenue in 2011. Product Line B was chosen as a suitable candidate for regional sourcing compared to other product lines primarily because of the anticipated demand growth in the Asia-Pacific region and worldwide as well as the potential capacity limitations beyond 2017. Certain issues were identified when evaluating the process complexity and the financial implications of expanding the manufacturing operations in the Asia-Pacific region. However, the Supply Chain Strategy Group believed that it was worthwhile to continue the evaluation based on the potential benefits of having another manufacturing location besides North America. Following the methodology, the first step is to review the sales forecasts that are available at Company X.

Regional & Global Demand

To understand the regional demand, sales forecasts were obtained and reviewed with the guidance of the subsidiary's Commercial and Finance Groups. Figure 10 shows the expected sales growth for various product lines in the Asia-Pacific region (note: the product lines have been designated with alphabetical letters, and the scale for the revenue has been removed to maintain the confidentiality of proprietary information for Company X):

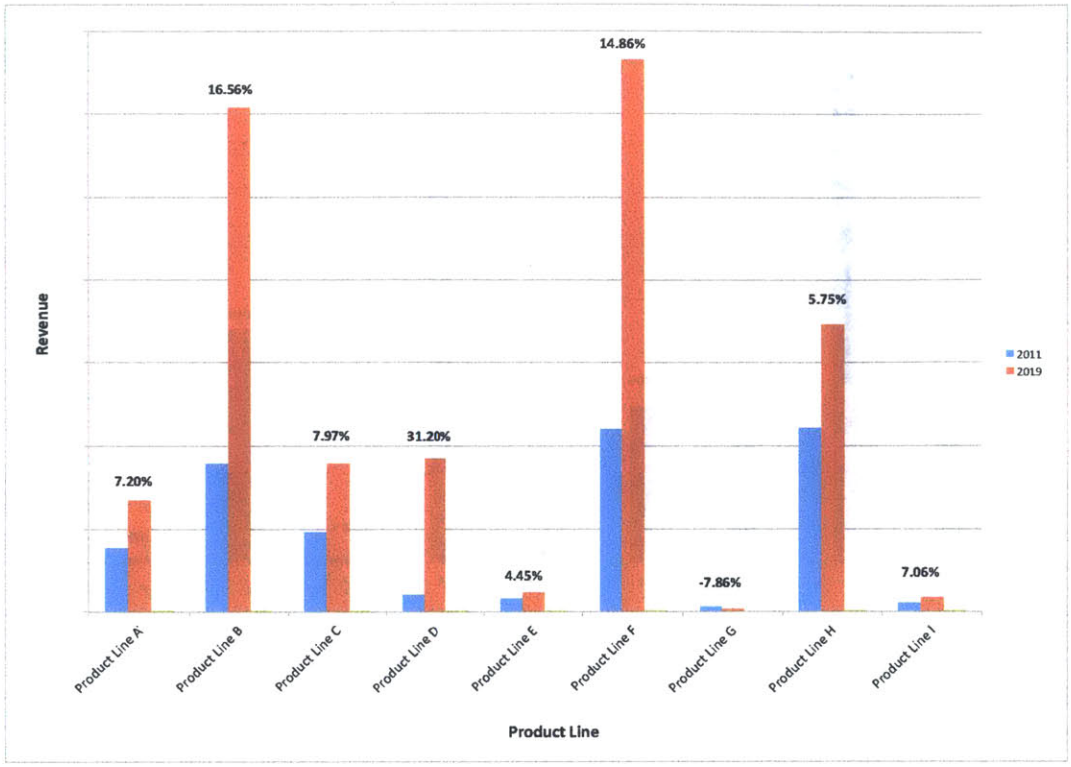


Figure 10 - Expected Product Line Growth in the Asia-Pacific Region for the Subsidiary

We can see that Product Lines B, D, and F have the highest growth rates. Product Lines B, F, and H are expected to be the top revenue drivers for the subsidiary in the region by 2019. These results were compared against the global revenue forecasts shown in Figure 11 below (note: once again, the scale for the revenue has been removed to maintain confidentiality of proprietary information for Company X):

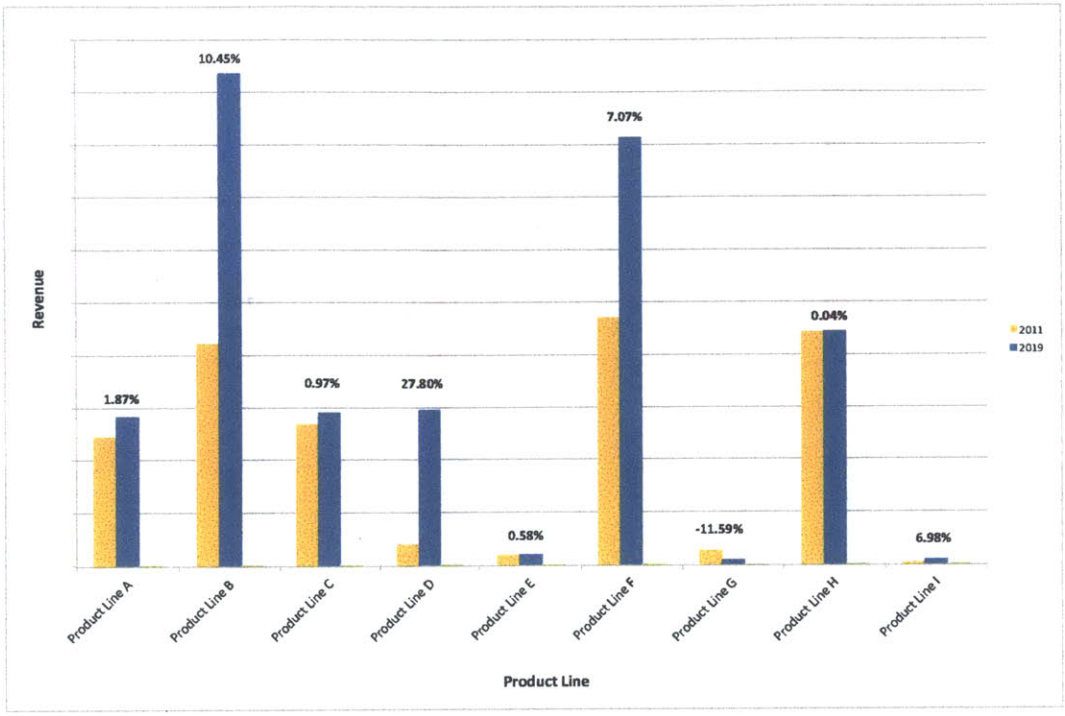


Figure 11 - Expected Product Line Growth Worldwide for the Subsidiary

In this case, we see that the global growth rates are generally not as high as the regional growth rates. However, there is a strong correlation between the regional growth rates and the global growth rates for the product lines evaluated ($r = 0.981$), signifying that a products with high global growth rates will likely have high regional growth rates and vice-versa.

Of the products lines evaluated, Product Lines C and H have market-appropriate products that are currently being sold or developed. However, a contract manufacturer is currently manufacturing those products, and the External Operations Group confirmed that it is unlikely that manufacturing for these products would be brought back in-house. Similarly, manufacturing operations for Product Lines G and I are also outsourced to a contract manufacturer, but there is less incentive to manufacture those products internally due to low projected revenues versus the costs required to manufacture them in-house. Therefore, the opportunity for the Supply Chain Group to manufacture those products (market-appropriate products for Product Lines C and H as well as all products for Product Lines G and I) in the region is minimal at this time. There is still the potential opportunity to manufacture other product models

for Product Lines C and H. However, after evaluating the current network capacity, which is explained in the upcoming section, the need for additional capacity to meet future demand for those product lines does not currently exist.

Current Network Capacity

Figures 12 and 13 show the expected capacity utilization rates for each manufacturing production line based on the modified global demand volume forecasts in the optimistic scenario. This data was created and is maintained by the Manufacturing Group within the Supply Chain Group. These rates do not take into consideration capacity for the packaging and sterilization operations. However, the Manufacturing Group confirmed that the required capacity for those operations would be available over the five-year horizon (i.e., less than 80% utilization over that timeframe).

The capacity utilization rates show the percentage of time that the production lines will need to be operated in order to meet global demand, assuming with no major operational delays. The total amount of time available for each manufacturing line is 80 hours per week (the plant normally operates 16 hours per day from Monday through Friday). Any time above 80 hours per week is considered overtime at that location. The Manufacturing Group within the Supply Chain Group strives to keep the capacity utilization rates of between 30% and 80% (green). Below 30% (yellow) is a clear indication of excess capacity for the manufacturing line. Utilization between 80% and 100% (blue) is an indication that the capacity will become limited if demand continues to grow and no process improvements are made. When capacity is above 100% (red), it means that additional shifts will be required to meet demand.

Based on this information reviewed, certain stock-keeping units (SKUs) for Product Line B could potentially face capacity constraints within the five-year horizon more so than other product lines. This means that unless steps are taken to increase productivity or output within the next four to five years and depending on forecast accuracy, there is a chance that customer demand will not be met. The current

operations in North America will be able to support the global demand for the other product lines even with no changes to work scheduled (i.e., not going beyond 80 hours per week).

Manufacturing Line by Product Line	Utilization Target	2012	2013	2014	2015	2016	2017
Product Line A							
Manufacturing Line 1	80%	**18%**	**26%**	**14%**	**15%**	**15%**	**14%**
Manufacturing Line 2	80%	**2%**	**4%**	**1%**	**1%**	**1%**	**1%**
Manufacturing Line 3	80%	77%	76%	50%	50%	50%	50%
Manufacturing Line 4	80%	34%	34%	**22%**	**22%**	**22%**	**22%**
Manufacturing Line 5	80%	48%	48%	35%	35%	35%	35%
Manufacturing Line 6	80%	68%	70%	43%	44%	44%	44%
Manufacturing Line 7	80%	66%	68%	47%	47%	47%	47%
Product Line B							
Manufacturing Line 8	80%	75%	75%	78%	83%	89%	94%
Manufacturing Line 9	80%	50%	46%	48%	51%	55%	58%
Manufacturing Line 10	80%	61%	60%	63%	67%	71%	76%
Manufacturing Line 11	80%	78%	77%	81%	86%	92%	98%
Manufacturing Line 12	80%	**27%**	31%	32%	34%	36%	39%
Manufacturing Line 13	80%	75%	87%	92%	97%	104%	110%
Manufacturing Line 14	80%	36%	34%	35%	37%	40%	43%
Manufacturing Line 15	80%	84%	90%	90%	90%	90%	90%
Manufacturing Line 16	80%	111%	71%	75%	79%	85%	90%
Product Line C							
Manufacturing Line 17	80%	**14%**	**14%**	**10%**	**10%**	**10%**	**10%**
Manufacturing Line 18	80%	74%	81%	63%	56%	51%	54%
Manufacturing Line 19	80%	71%	67%	46%	46%	46%	48%
Manufacturing Line 20	80%	77%	72%	40%	41%	41%	43%
Manufacturing Line 21	80%	78%	73%	57%	58%	58%	61%
Manufacturing Line 22	90%	**27%**	**26%**	**17%**	**17%**	**17%**	**18%**
Manufacturing Line 23	80%	72%	68%	42%	42%	42%	44%
Manufacturing Line 24	80%	52%	48%	34%	34%	34%	36%
Product Line D							
Manufacturing Line 25	80%	58%	39%	38%	38%	37%	40%
Manufacturing Line 26	80%	58%	39%	38%	38%	37%	40%
Manufacturing Line 27	80%	58%	54%	40%	40%	40%	43%
Manufacturing Line 28	80%	90%	81%	85%	81%	84%	86%
Manufacturing Line 29	80%	76%	60%	71%	74%	75%	80%
Product Line E							
Manufacturing Line 30	80%	53%	51%	34%	34%	34%	35%
Manufacturing Line 31	80%	53%	50%	37%	37%	37%	37%

Figure 12 - Capacity Utilization for the Manufacturing Lines Associated with Product Lines A - E

Manufacturing Line by Product Line	Utilization Target	2012	2013	2014	2015	2016	2017
Product Line F							
Manufacturing Line 32	80%	**9%**	**8%**	**6%**	**6%**	**6%**	**6%**
Manufacturing Line 33	80%	**7%**	**7%**	**5%**	**5%**	**5%**	**5%**
Manufacturing Line 34	80%	**7%**	**9%**	**5%**	**5%**	**5%**	**5%**
Manufacturing Line 35	80%	**28%**	**29%**	**19%**	**20%**	**19%**	**20%**
Manufacturing Line 36	80%	82%	87%	89%	88%	90%	89%
Manufacturing Line 37	80%	**14%**	**22%**	**23%**	**22%**	**23%**	**25%**
Manufacturing Line 38	80%	**12%**	**11%**	**12%**	**14%**	**15%**	**13%**
Manufacturing Line 39	80%	**12%**	**15%**	**12%**	**11%**	**15%**	**14%**
Manufacturing Line 40	80%	71%	68%	68%	69%	68%	71%
Manufacturing Line 41	80%	54%	54%	41%	42%	41%	43%
Manufacturing Line 42	80%	**22%**	**20%**	**21%**	**21%**	**21%**	**22%**
Product Line G - Not Manufactured Internally							
Product Line H							
Manufacturing Line 43	80%	56%	60%	60%	60%	60%	60%
Manufacturing Line 44	80%	61%	39%	39%	38%	39%	38%
Manufacturing Line 45	80%	31%	32%	32%	32%	32%	32%
Manufacturing Line 46	80%	**29%**	33%	33%	33%	33%	33%
Manufacturing Line 47	80%	38%	39%	40%	40%	40%	41%
Manufacturing Line 48	80%	35%	36%	35%	35%	35%	35%
Manufacturing Line 49	80%	78%	80%	79%	79%	79%	79%
Manufacturing Line 50	80%	73%	71%	70%	70%	70%	70%
Manufacturing Line 51	80%	88%	72%	72%	71%	71%	71%
Manufacturing Line 52	80%	36%	34%	34%	34%	34%	34%
Manufacturing Line 53	80%	43%	42%	42%	42%	42%	42%
Manufacturing Line 54	80%	**25%**	31%	30%	30%	30%	30%
Manufacturing Line 55	80%	82%	62%	62%	61%	62%	62%
Manufacturing Line 56	80%	46%	46%	45%	45%	45%	45%
Manufacturing Line 57	80%	43%	43%	42%	42%	42%	42%
Manufacturing Line 58	80%	51%	**21%**	**21%**	**21%**	**21%**	**21%**
Manufacturing Line 59	80%	**26%**	**11%**	**10%**	**10%**	**10%**	**10%**
Manufacturing Line 60	80%	40%	35%	34%	34%	34%	34%
Manufacturing Line 61	80%	46%	43%	42%	42%	42%	42%
Manufacturing Line 62	80%	31%	31%	31%	30%	31%	30%
Manufacturing Line 63	80%	37%	38%	37%	37%	37%	37%
Manufacturing Line 64	80%	82%	82%	79%	76%	75%	77%
Manufacturing Line 65	80%	86%	86%	76%	75%	72%	75%
Manufacturing Line 66	80%	65%	60%	62%	60%	61%	60%
Manufacturing Line 67	80%	85%	85%	84%	82%	80%	81%
Product Line I - Not Manufacturing Internally							

Figure 13 - Capacity Utilization for the Manufacturing Lines Associated with Product Lines F - I

Process Complexity

The evaluation of process complexity provided key insights into the various product lines for the subsidiary. Overall, there were concerns regarding the IP rights and the locations of current suppliers for the product lines. However, since the potential investment costs and the required operating capabilities

would not be significant compared to those required for other subsidiaries at Company X, the potential benefits of having another manufacturing location could potentially outweigh these risks for certain product lines. Table 4 presents the observations that were made during the implementation of this part of the methodology:

Table 4 - Process Complexity Assessment for the Subsidiary

Evaluation Criteria	Key Observations
Regulatory Classification	• All product lines are FDA Class II devices, meaning that registration requirements are relatively straightforward in the Asia-Pacific region except in China).
IP Rights	• Only Process Technology A (described in Chapter 5) requires stronger IP protection versus the other process technologies and unit operations required. As mentioned in Chapter, certain leaders at Company X would consider placing this technology in the region with the assumption that the sites could handle the IP protection requirements.
Process Maturity	• Process maturity is variable at the SKU level for most of the product lines. • Product Line H is generally considered to be the most mature (later stages of their product lifecycles). • Product Line D is generally considered the least mature (newest product line).
Operating Capabilities Required	• No major internal capabilities are required compared to the operational requirements for the other medical device subsidiaries at Company X.
Investment Required	• The investment in equipment and building construction would be significant when compared the requirements of the other medical device subsidiaries at Company X.

Cost & Time Benefits

Through the evaluation of the current costs and lead times for products shipped to the Asia-Pacific region, we find that the financial benefits for expanding in the region are somewhat limited

besides the ability to reduce logistics costs by meeting free trade agreements within the region. Table 5 highlights the observations made:

Table 5 - Cost & Time Benefits Assessment for the Subsidiary

Potential Benefits	Key Observations
Lead Time	• Since all finished goods are shipped to the regional distribution center by air, the change in lead times would only be a few days. This also assumes no interruptions or delays in raw material supply.
Proximity to Suppliers	• A majority of current suppliers are based and manufacture materials in North America. Developing the local supplier capabilities in the Asia-Pacific region would require significant resources (cost and time).
Operating Costs	• Since the current North American operation already utilizes a location with low labor and utility costs, there will not likely be a significant decrease in these costs when compared to a new location in the Asia-Pacific region. • Across all product lines, labor costs (direct and indirect) account for less than 5% of the production costs. This is significantly lower than the labor cost percentage for other medical devices at Company X.
Logistics Costs	• Although the finished goods shipping costs from a new Asia-Pacific location to the regional distribution center will be less, the raw material shipping costs will likely be higher since a significant percentage of products will continue to be shipped from North America (the exact percentage varies for each scenario in the decision analysis). • Due to the current North American location, Company X is not able to take advantage of certain free trade agreements that are available in certain countries within the Asia-Pacific region. This would allow the company to pay lower rates for import duties and taxes. In order to meet these agreements, however, the External Operations Group must meet specific procurement requirements (e.g., it must source at least 65% of raw materials from the Asia-Pacific region), which vary for each country.
Tax Strategy	• For all of the products lines evaluated, the income tax rates are not likely to change. Further details cannot be revealed in order to maintain confidentiality.

Selecting the Product Line(s)

Once all of the data was gathered, members of the Supply Chain Strategy Group reviewed it to gain a better overall picture. Based on the information derived as part of this case study, Product Line B was identified as a candidate for regional sourcing. In addition to being a key growth driver in the region and worldwide, it will be the first product line for the subsidiary to face capacity constraints with the existing North American operations. The primary risks identified in this evaluation were the IP rights with Process Technology A and the development of a robust procurement strategy given the distance from current supplier locations. However, due to the expected demand and potential capacity restrictions over time, it was determined to be the most suitable candidate at this time.

6.2 Evaluating Where the Products Should Be Manufactured

In this phase of the methodology, five locations were selected for further analysis using the framework discussed in Chapter 3.2. Since the Supply Chain Group already has manufacturing operations in China and India, selecting a site in each country was warranted in order to align with the preferred campus approach and because of the proximity to the end-users of the devices. Locations in Malaysia, Thailand, and Singapore were also considered as part of this analysis. Thailand was eliminated from consideration due to environmental stability issues (e.g., flooding), minimal operational capabilities currently in existence, weak IP protection, and potential language barriers. In addition, Singapore was eliminated based on the high operating costs compared to the other locations. At this time, no countries in the Asia-Pacific region explicitly require domestic production of medical devices in order to sell products in that country. Countries with such regulations would have been included in this part of the analysis if this had been the case. Tables 6 and 7 show the benefits and risks for each of the locations that were considered as follows:

Table 6 - Benefits & Risks for the Malaysia & China Locations

		Operating Capabilties	Ability to Meet Regulatory & Government Requirements	Political & Environmental Stability	Cost Implications
Chosen Location in Malaysia	**Benefits**	*Another group within the division has a manufacturing presence *Current suppliers with manufacturing locations (sterilization and plastics primarily) *"Up-and-coming" location for the medical device industry *Minimal cultural issues	*No major issues identified for the specific location	*Government has strong support (i.e., political stability) *No major environmental issues identified	*Government incentives (e.g., exempt from raw material import duties, aid in construction costs) *Low operating costs (labor, overhead) *Proximity to the regional distribution center in Singapore
	Risks	*No existing presence for the Supply Chain Group		*Minor ethnic tensions in the past	*Expected currency appreciation *High setup costs (capital project)
Chosen Location in China	**Benefits**	*Existing presence for the Supply Chain Group *Current supplliers with manufacturing locations (plastics and electromechanical primarily)	*Company X has developed relationships with the local agencies with its previous experience in the area	*No major issues identified for the specific location	*Leverage infrastructure at the existing site
	Risks	*Weak IP protection *Only one contract sterilizer identified *Cultural issues identified (employee turnover, language barrier, etc.)	*Additional clinical trials required to sell products domestically (~1 year delay)		*High operating costs (labor, overhead) versus other locations in China *Expected wage and price inflation *Expected currency appreciation *Raw material import duties are high

Table 7 - Benefits & Risks for the India, Thailand, & Singapore Locations

		Operating Capabilties	Ability to Meet Regulatory & Government Requirements	Political & Environmental Stability	Cost Implications
Chosen Location in India	Benefits	*Existing presence for the Supply Chain Group	*No major issues identified for the specific location	*No major issues identified for the specific location	*Leverage infrastructure at the existing site *Low setup costs (i.e., shell space exists)
	Risks	*Weak IP protection *Current suppliers do not have local manufacturing locations *Only one contract sterilizer identified *Minimal additional space for other product lines beyond Product Line B			*Raw material import duties are high *Expected price inflation
Chosen Location in Thailand	Benefits	*Some suppliers have locations (e.g., sterilization contractors)	*No major issues identified for the specific location	*Current government has strong support (i.e. political stability)	*Lower operating costs (labor, overhead)
	Risks	*No existing presence for the Supply Chain Group *Only one contract sterilizer identified *Weak IP protection *Potential language barrier		*Potential flooding in certain regions *Political issues in the past	*High setup costs (capital project)
Chosen Locatin in Singapore	Benefits	*Life science industry cluster *Strong IP protection *Minimal cultural issues	*No major issues identified for the specific location	*No major issues identified for the specific location	*Location next to the regional distribution center *Potential long-term tax advantages
	Risks	*No existing presence for the Supply Chain Group *No sterilization contractors identified			*High operating costs (labor, overhead) versus other locations *High setup costs (capital project)

6.3 Evaluating How the Supply Chain Should Be Organized

As part of the methodology, the next step is to decide how the supply chain operations for manufacturing Product Line B would be designed. The option to outsource all manufacturing operations was ruled out due to the following reasons:

1. Intellectual property rights associated with Process Technology A
2. High profit margins for the product line in general
3. New pipeline products with uncertain demand profiles

Once that decision is made (typically as part of the business process), the current supply chain can be evaluated to determine what is required for all unit operations in the manufacturing process. This information can then be used to develop the supply chains and project costs for each location. Based on the locations selected in Chapter 6.2, the supply chains for the following options were developed:

1. **Malaysia**: Build a "greenfield" site in at a selected location in Malaysia
2. **China**: Build a new manufacturing facility on an existing campus in China
3. **India**: Retrofit the current space in an existing facility in India

Each of the elements of the value chain specified in Chapter 3.3 was analyzed in order to develop the supply chains for each option. The insights gained from the analysis and the supply chain development overall are presented below.

Procurement & Inbound Logistics

Since suppliers have already been identified for the needed raw materials, the External Operations Group expected to continue using those suppliers rather than find new local suppliers immediately. This could change after the new facility has been operating after several years, but it was not accounted for as part of the case study due to complications around determining which suppliers would change. Since some of the current suppliers already manufacture these materials in the Asia-Pacific region or have the capability of doing so, inbound transportation costs could be reduced. The inbound transportation costs varied under each scenario as part of the decision analysis. For example, all raw materials would need to be shipped from North America under the pessimistic scenario (i.e., suppliers would not shift manufacturing locations or change lanes). Further details are provided in Tables 11 and 12 in Appendix A. All inbound shipping from North America initially would be done via air freight as per the recommendations of the Transportation and Manufacturing Groups. Although the transportation costs

would be higher compared to ocean freight, both groups wanted to maintain short lead times for the required raw materials.

Operations & Technology Development

Figure 14 below provides an illustration of the key steps and unit operations for the full production process of Product Line B and what is conducted at the current sites in North America (notes: sites are designated as A and B to maintain confidentiality):

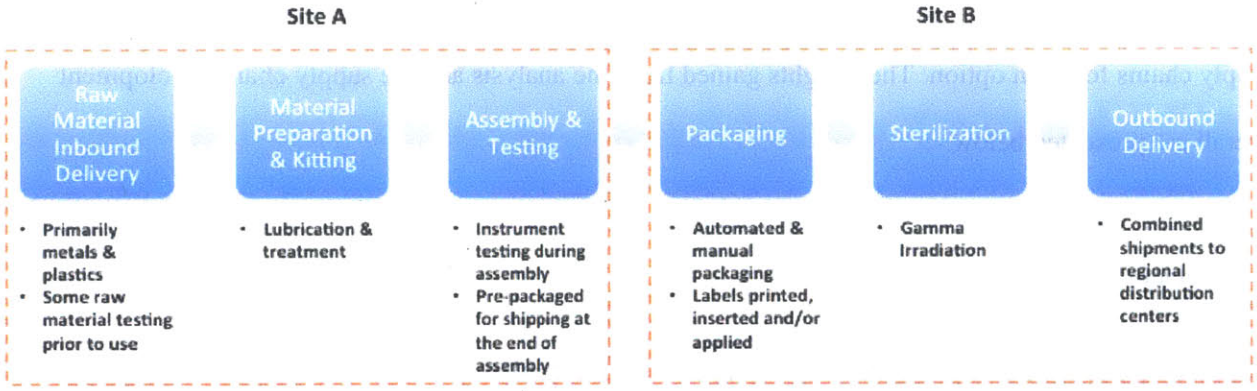


Figure 14 - Overview of the Current Supply Chain for Product Line B

Two sites are currently used to execute the full manufacturing process. In-transit transportation is completed with truck shipments from Site A to Site B, and the travel time is approximately 5 hours. For the selected locations in the Asia-Pacific region, the new model integrated the packaging and assembly operations at one site, as opposed to using two separate sites, and utilized a sterilization contractor instead of building the capabilities in-house. The packaged products would be transported to the sterilization contractor via truck. Not only would this save on capital expenditure (i.e., not investing in a sterilization facility) but it also reflects the current viewpoint of the Supply Chain Group regarding sterilization process technology. As part of a separate project, the Manufacturing, External Operations, and

Manufacturing Engineering Groups are working together to identify and utilize contractors for sterilization activities that are not considered a core process technology.

To avoid additional development costs, it was decided that the unit operations at the Asia-Pacific locations should be fully replicated based on the existing systems as opposed to modifying the processes specifically for each location. This means that the SKUs associated with Product Line B would be manufactured according to the same processes with identical equipment. This is a significant advantage for product registration in each of the Asia-Pacific countries served because the regulatory authorities could require further validation testing if process modifications are made. This would add an additional three to six months, as estimated by the Manufacturing Engineering Group, to the overall project timeline. Moreover, if the manufacturing processes are identical, it becomes easier to troubleshoot equipment problems and make process improvements at both the North American and the Asia-Pacific locations.

A full production lot for both the instruments and the consumable components can be currently produced within 24 hours for almost every SKU at Site A. This includes material preparation, assembly, testing, and packaging. Production yield rates are typically above 95% for all of the manufacturing lines as well. Since the same type of equipment is being used, in addition to such high productivity levels for these manufacturing lines currently, the Engineering Group estimates that 90% of the global demand for Product Line B could be handled with the same production lines included in the new facility. However, the labor force would need to be significantly increased in order to handle the scale required to meet 90% of the global demand.

Outbound Logistics

As part of the current supply chain, all finished goods are shipped from North America to the regional distribution center in Singapore via air freight. Similarly to decisions around inbound freight, the Manufacturing and Transportation Groups wanted to minimize the lead times for Product Line B to customers. Both groups recommended using air freight to transport finished goods from China and India

to the regional distribution center. On the other hand, for the selected location in Malaysia, finished goods would be shipped via truck to the regional distribution center. In addition to being less expensive than by using air freight, the difference in lead times is minimal (i.e., a few hours).

Firm Infrastructure & Human Resource Management

As mentioned before, the Supply Chain Group has existing manufacturing operations in India and China. Therefore, developing capabilities in both locations would meet the group leadership's desire for a campus approach. The Malaysia option, on the other hand, is considered a "greenfield" site since there is no existing infrastructure for the Supply Chain Group. This means that the group would need to build the required infrastructure from scratch (e.g., purchase land, hire a new labor force, install new information technology (IT) systems). Hence, the project costs would be higher compared to the other options. Though, as referenced in Table 6 in Chapter 6.2, the Supply Chain Group can leverage the experience of other another group within the Supply Chain Division that has a presence in Malaysia.

With respect to long-term growth opportunities at the selected Asia-Pacific locations, both the China and Malaysia options have ample growth capacity to accommodate new product lines at some point in the future. On the other hand, the India option has limited capacity beyond what is required to manufacture Product Line B. This is because the existing facility only has enough space for the equipment required for manufacturing that product line. If the Supply Chain Group wanted to expand its manufacturing capabilities in India beyond those required for Product Line B (i.e., adding additional product lines in the future), it would need to build a new facility. Although this does not affect the analysis performed as part of this case study, it would be a major consideration if other product lines were identified as sourcing candidates during the "What" phase (only Product Line B was identified).

With the proposed supply chain and locations identified, estimates for the potential project cost were gathered with help from various experts across Company X. Table 8 provides breakdown of the one-time project costs for each of the locations (note: all costs are in U.S. Dollars and rounded):

Table 8 - Overview of Project Costs for Each Location

	Malaysia	China	India
Land Ownership	$8,850,000.00	$-	$-
Construction	$18,400,000.00	$15,650,000.00	$4,100,000.00
IT Infrastructure	$9,000,000.00	$9,000,000.00	$9,000,000.00
Process Equipment	$23,500,000.00	$23,500,000.00	$23,500,000.00
Construction Logistics	$1,200,000.00	$1,200,000.00	$1,200,000.00
Engineering Services	$5,000,000.00	$5,000,000.00	$5,000,000.00
Company X Services	$5,000,000.00	$5,000,000.00	$5,000,000.00
Commissioning & Validation	$500,000.00	$500,000.00	$500,000.00
Regulatory Affairs	$200,000.00	$1,500,000.00	$200,000.00
TOTAL	**$71,650,000.00**	**$61,350,000.00**	**$48,500,000.00**

The Malaysia option carries the highest cost since it is a "greenfield" project. On the other hand, since the India option involves retrofitting an existing space, the costs are expected to be lower. As mentioned earlier, no engineering modifications would be required for the North American operations (Sites A & B). Site A could instead add an additional shift to meet the increased demands, assuming that the forecasted scenario occurs, for SKUs of Product Line B. Site B already has the capacity and labor to handle the additional demand. The Finance Group estimates that it would cost an additional $500K per year in operating costs (labor and overhead) to add an additional shift at Site A to meet that demand. However, Company X would continue to single-source Product Line B. This is further evaluated as part of the decision tree analysis in Chapter 6.4.

The facility design for each of the three locations includes all the required assembly lines and material preparation equipment that would be required to support demand for all SKUs of Product Line B in the Asia-Pacific region. The Operations & Technology Development section above includes details regarding the decisions made for the specific unit operations. The decision tree analysis accounts for the additional capacity available when evaluating a potential failure in the supply chain. Using the results

from the operations analysis and project cost estimates, decision analysis tools can be applied to determine which of the scenarios represents the best path forward for Company X.

6.4 Decision Analysis Results

Appendix B includes all of the calculations for each of the three decision analyses completed. The following options were analyzed with the decision analysis tools (total landed cost analysis, NPV analysis, and decision tree analysis) to determine if there was a strong financial case for manufacturing Product Line B in the Asia-Pacific region:

1. **Malaysia**: Establish a manufacturing presence at a selected location in Malaysia
2. **China**: Build a new manufacturing facility on an existing campus in China
3. **India**: Retrofit the current space in an existing facility in India
4. **North America**: Continue to ship product to the Asia-Pacific region from the existing site(s)

Overall, the most cost-effective option is to continue meeting regional demand for Product Line B with the current North American operations versus establishing a manufacturing location in the Asia-Pacific region. This was confirmed by the results from all of the decision analyses. The results for each analysis are detailed in this section.

Landed Cost Analysis Results

The total landed costs from each manufacturing location to the regional distribution center in 2019 was determined as part of this analysis. The year 2019 was chosen because of the time required to complete the required the various capital projects and the availability of sales forecasts up to that point. For Company X, this year will change since a new seven-year sales forecast is created annually (e.g., if the analysis were conducted in 2013, 2020 would be the year to evaluate the costs). The total landed cost

includes all associated manufacturing and supply chain costs as outlined in the "How" phase. Figure 15 illustrates how the costs varied between the three scenarios (note: the term "box" is used to describe the typical selling size for various SKUs of Product Line B):

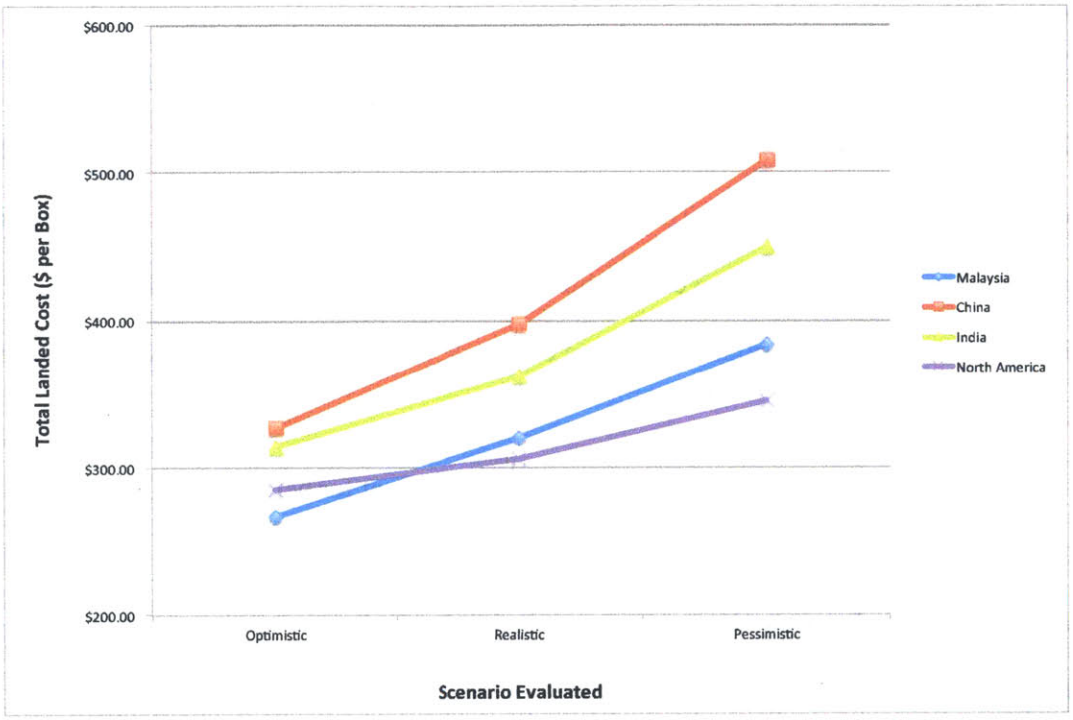


Figure 15 - Total Landed Costs for Each Scenario Evaluated

We see that the current North American operation maintains the lowest total landed cost in the realistic and pessimistic scenarios while Malaysia has the lowest total landed cost in the optimistic scenario. On the other hand, China has the highest total landed cost in all scenarios, even with a significant percentage of expected sales. One of the main reasons that the North America option has a lower total landed cost is the fact that there are sunk costs at the existing sites. Much of the equipment and facility depreciation costs, which are fixed costs, have already been incurred. On the other hand, with the new construction and equipment installations required for options in the Asia-Pacific options, those locations would incur higher depreciation costs in 2019.

The full breakdown for the total landed costs cannot be given in order to further maintain the confidentiality of proprietary information for Company X. However, the following is an overview of those results for all three scenarios:

- Direct labor accounts for between 3% (Malaysia, India, North America) and 9% (China) of the total landed costs. This is not representative of the typical cost structures for other medical devices sold by Company X. Moreover, it demonstrates the higher relative labor costs in China as compared to the other locations. The manufacturing location in China is an area where the labor costs are much higher than the average labor costs for the rest of the country. In fact, the expected labor costs in this area are higher than those of Site A, which benefits from an area with low labor costs, in North America.
- Freight costs, both inbound and outbound combined, account for between 4% (Malaysia, North America) and 8% (China) of the total landed costs. This is in line with some of the other device cost structures for Company X. In addition, it highlights the higher relative transportation costs to and from China.
- Overhead costs are the second-largest costs behind material costs. As discussed before, this is primarily attributed to the depreciation costs at each location.
- Expected duties and import taxes make up between 11% and 23% of the total landed costs, depending on the location and the scenario. Since the Malaysia option does not have any duties or taxes on raw material imports as per the allowed incentives by the government, this provides a significant advantage. Moreover, if free trade agreements are satisfied, the expected costs are reduced even further. The sensitivity analysis in Chapter 6.5 provides further details as to what the probability should be in order for the Malaysia option to have the same total landed cost as the North America option.

NPV Analysis Results

Details regarding the NPV analysis can be found in Appendix B. Figure 16 shows the NPV for each new manufacturing locations evaluated under the three scenarios (note: the North America option is not included because no facility or engineering modifications are actually required to increase output for Product Line B):

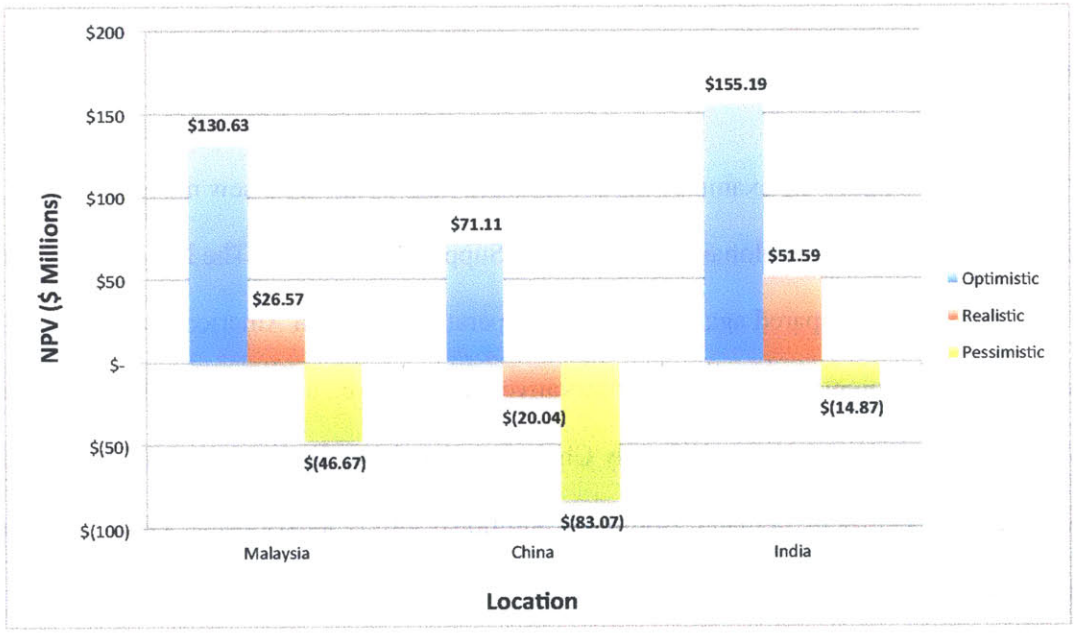


Figure 16 - NPV Results for Each Location Evaluated

We see that the India option has the highest NPV in all three scenarios. This is due to the fact that the India option has the lowest one-time project costs of the three Asia-Pacific locations as discussed in the Firm Infrastructure & Human Resource Management section of Chapter 6.3. However, as mentioned in the same section, the India option does not allow for expansion opportunities beyond Product Line B as would the Malaysia and China options. A new manufacturing facility would need to be built in India if additional product lines were to be manufactured in the country.

The NPV range, between the optimistic and pessimistic scenarios, is relatively similar for all three of the locations. Of the three options in the realistic scenario, the expansion in China is the only one that has a negative NPV. This is due in large part to the higher operating costs overall and the time required for conducting the mandatory clinical trial that results in an increased project timeline. Appendix A provides further insights into what changes to the risk factors and uncertainties could yield a positive NPV.

Decision Tree Analysis Results

The decision tree analysis examines the benefits and risks of having a new manufacturing location for Product Line B in the global network for the Supply Chain Group. The NPV values of the Asia-Pacific options were compared against the current operations in North America. Based on the expected capacity requirements and taking a conservative approach (i.e., uncertainty regarding whether the sales forecast would be achieved), the Supply Chain Strategy Group looked into the option of adding an additional shift to meet future demand. Adding an additional shift (approximately $500K per year) at Site A is cheaper than expanding in a new location. However, products will continue to be single-sourced, which is seen as a significant risk by senior leaders of the subsidiary.

Working with the Supply Chain Strategy Group, estimates were gathered to determine the probability of plant failure within the NPV time horizon (10 years). Furthermore, the group was able to help in estimating the probability of a major failure (i.e., not able to manufacture for at least 1 year) versus a minor failure (i.e., not able to manufacture for at least 3 months). A major failure includes issues such as a major product recall or a hazardous incident (e.g., a plant fire), and a minor failure could be attributed to a minor product recall or an equipment failure. Multiple failures within the same time horizon were not accounted for in this analysis as per the Supply Chain Strategy Group's recommendation. The team also estimated that it would cost an additional $75M to address an issue relating to a major failure and $30M to fix one relating to a minor failure. Appendix B includes a

breakdown of the applied decision tree and the values. Table 9 shows the expected outcomes for this analysis:

Table 9 - Outcomes from the Decision Tree Analysis

Options Analyzed	Expected Value
1 - Expand in Malaysia	$27,699,001.23
2 - Expand in China	($19,586,897.14)
3 - Expand in India	$54,299,664.35
4 – Continue with North American Operations	$69,939,529.77

We see that it is initially more favorable to continue manufacturing at the location in North America (i.e., adding another shift) as opposed to expanding in any of the Asia-Pacific locations, thereby providing for dual sourcing. Of the three expansion options, the expansion in India was favored because this option had the highest NPV values in every scenario (optimistic, realistic, and pessimistic). Along the same lines, the expected value for the expansion in China is negative because of the negative NPV values in the realistic and pessimistic scenarios. It is important to note that this evaluation only considers expansion options for Product Line B and no other product lines. The expected value of an expansion option would increase if other product lines were included in the future. Chapter 6.5 includes the sensitivity analysis conducted in order to determine when it would be more favorable for regional expansion.

6.5 Sensitivity Analysis for the Results

Although the results from the decision analysis suggest that it is preferable to continue shipping SKUs of Product Line B manufactured in North America to the Asia-Pacific region versus building a new manufacturing location in the region, it is worthwhile to determine how the decision could change as risk factors and other uncertainties are varied. A sensitivity analysis was conducted for this reason. The focus of the sensitivity analysis was on the landed cost and the decision tree results. For the landed costs, the values for all other risk factors and uncertainties were those identified for the realistic scenario.

Sales Forecast Variation

Figure 17 illustrates how the total landed cost changes as the sales forecast varies by changing the scaling factor ("F") in the equation used to calculate the sales growth rate (see the Revenue section of Appendix A for further details):

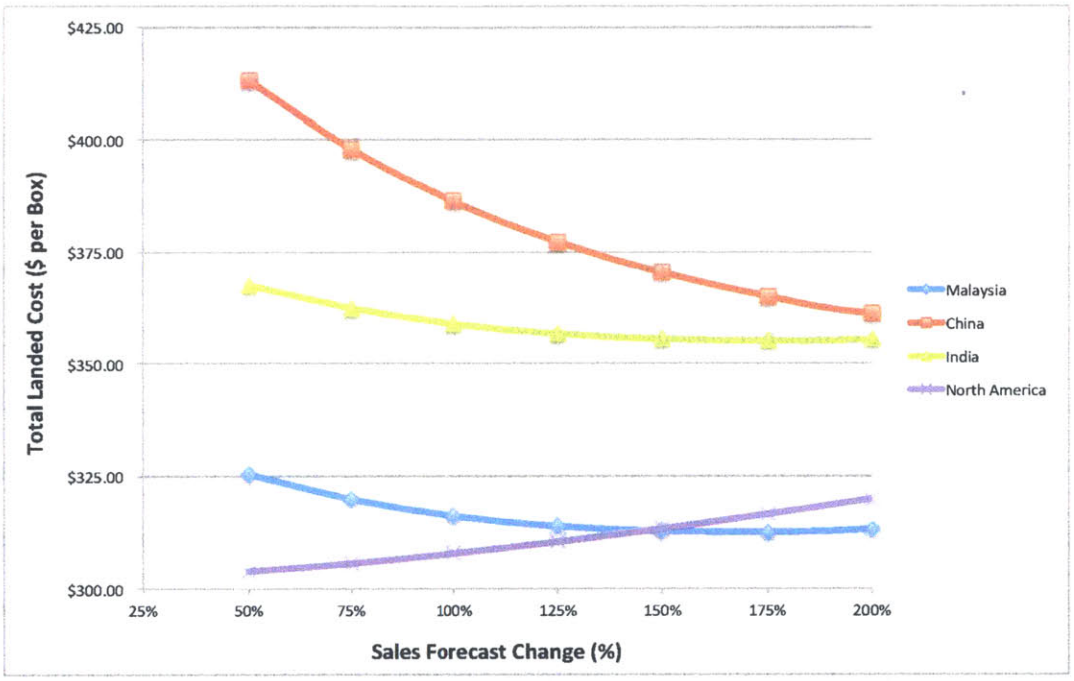


Figure 17 - Total Landed Cost Versus Changes to the Sales Forecast

We see that a significant increase in sales is required in order for the Asia-Pacific manufacturing locations to achieve a lower total landed cost in one of the expansion options. For example, we would need a 45.9% increase above the current sales forecast (assuming 100% satisfied, i.e., the value used for the optimistic scenario) in order for the Malaysia option to be competitive with the current North American operations As it is, the expected sales forecast change determined for the realistic scenario is 25% lower than the current sales forecast (i.e., 75% of the original forecast) based on the input from the Financial and Commercial Groups at Company X.

Based on the breakdown for the total landed costs between the Malaysia and North America options, the expected costs for import duties and taxes become greater for the North America option as demand increases (note: the actual breakdown cannot be revealed to maintain confidentiality of proprietary information for Company X). The Transportation Group confirmed that several countries in the Asia-Pacific region charge higher rates for products shipped from North America compared to products shipped from Malaysia. For the China and India options to be competitive with the North America option in terms of total landed cost, the change in the sales forecast would need to be much greater than 200% (i.e., essentially more than double the growth rates of the current forecast). The Commercial Group commented that this type of growth for an existing product line that has been sold in the Asia-Pacific region for several years in unrealistic.

Variation in Import Duties & Taxes

The expected costs for import duties and taxes at each location make up approximately 11% to 23%, depending on the location and the scenario, of the total landed costs for Product Line B. One way that these costs could be lowered is if the qualification requirements for free trade agreements are met in various countries across the region. The Transportation Group confirmed that at least 65% to 80% of the materials used in production must be sourced locally or from vendors of an approved location in order to meet the requirements for the agreements. Assuming that this can be done, the savings will have a major impact as per Table 10 below (note: total landed costs are shows in total rather than cost per box):

Table 10 – Cost Savings with Free Trade Agreements

	No Free Trade Agreements in Place	Free Trade Agreements in Place	Potential Savings
Malaysia	$ 101,663,027.80	$ 94,846,936.47	$ 6,816,091.33
China	$ 126,767,863.92	$ 124,849,836.87	$ 1,918,027.06
India	$ 115,265,359.80	$ 115,173,662.11	$ 91,697.70
North America	$ 97,140,389.05	$ 97,050,614.71	$ 89,774.33

The Malaysia option has the highest potential savings of all options reviewed. Treating the cost savings as an expectation, we would need a 66.4% chance of achieving all savings in order for the total landed cost of the Malaysia option to be less than the current North American landed cost. However, this endeavor would require significant changes to the current procurement strategy, since a significant percentage of raw materials are sourced from the U.S. Changing suppliers and/or convincing current suppliers to establish manufacturing facilities closer to a new location in the Asia-Pacific region will be difficult. One senior leader in the External Operations Group commented on the difficulty of successfully doing either unless extensive resources were available. This is further discussed in Chapter 7 as part the further considerations going forward.

Variation in Currency Depreciation

In this analysis, the effects of long-term currency changes were evaluated. Although none of the expansion options will be favored if the local currency appreciates versus the U.S. Dollar, it is worthwhile to review the scenarios to determine if any options become favored with currency depreciation. Figure 18 shows how the total landed costs would change as a result of long-term currency changes at each of the Asia-Pacific options:

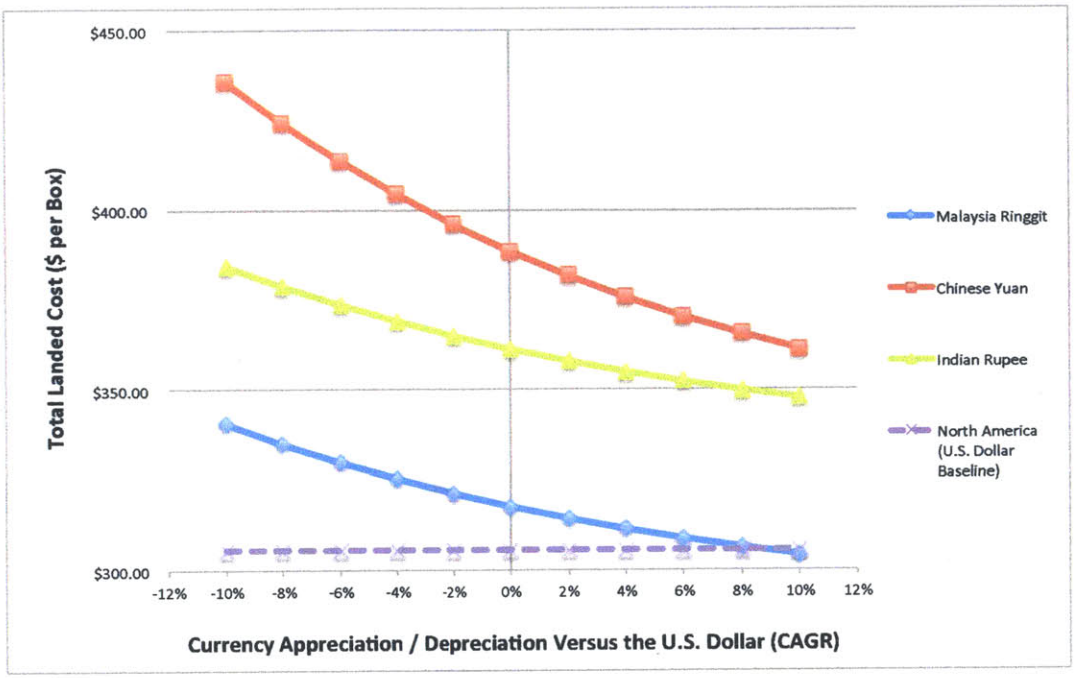


Figure 18 - Total Landed Cost Versus Changes in Currency Appreciation / Depreciation

We see that the Malaysia option becomes favored if the local currency (Malaysian Ringgit) depreciates annually by 8.6%. Such a dramatic change is unlikely over the long term, since the Ringgit has appreciated over the last eight years versus the U.S. Dollar. In addition, the total landed costs for the China and India options will only reach a total landed cost of approximately $333 with increasing currency depreciation. This is due to the fact that many of the transactions are completed in U.S. Dollars rather than the local currency. Moreover, since Company X maintains accounts across the globe and can pay a certain amount in local currencies (i.e., no immediate need to convert U.S. Dollars), it may be able to hedge against currency appreciation in certain circumstances.

Variation in Fuel Inflation

Although the Transportation Group confirmed that real freight inflation does not change over long periods of time, freight prices are still subject to fuel inflation or deflation. However, since freight only makes up less than 7% of the total landed costs in most cases, any minor changes will not influence

the total landed costs overall. Figure 19 proves that only a significant change in fuel inflation will yield a lower landed cost for the Malaysia option:

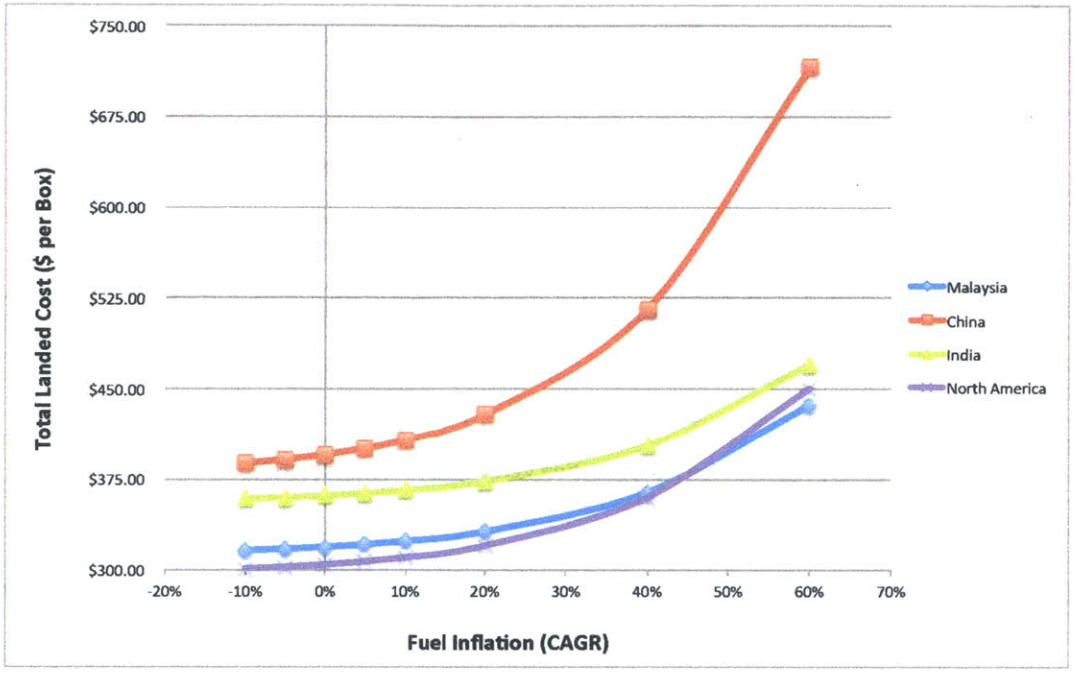


Figure 19 - Total Landed Costs Versus Changes to Fuel Inflation Rates

Achieving a 45.9% annual fuel inflation rate is unrealistic over the long term. Therefore, we can conclude that fuel inflation will not influence the decision overall.

Variation in Wage Inflation / Deflation

Similarly to freight costs, both direct and indirect labor do not have a significant impact on the total landed cost. As a result, increased wage deflation will not change the outcomes as evidenced in Figure 20 below:

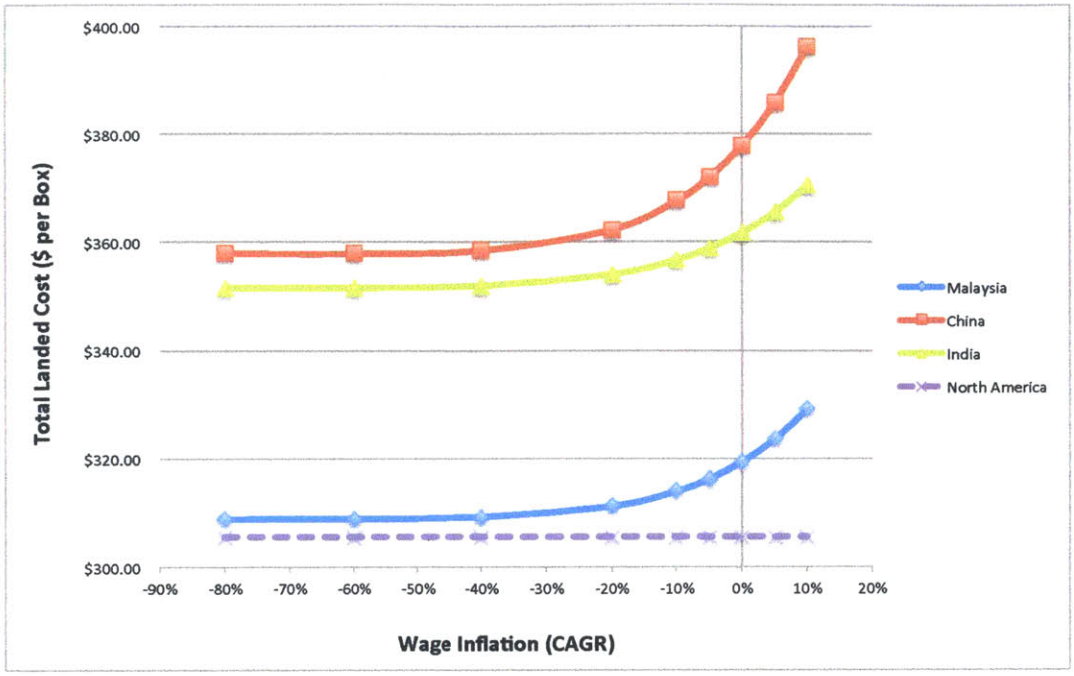


Figure 20 - Total Landed Cost Versus Changing Wage Inflation / Deflation

Increasing wage inflation rates will still lead to the North America option having the lowest total landed cost, and wage deflation (i.e., negative wage inflation) itself is uncommon. Moreover, the total landed costs for the China and India options will plateau even if wage deflation increases beyond 40%. The Finance Group has never seen wage inflation or deflation hit such extreme rates, so it can be concluded that wage inflation will not significantly influence any decision made.

Sensitivity Analysis of the Decision Tree

The sensitivity of a variety of uncertainties was reviewed using TreeAge™ Pro, which is the software used to create and evaluate the decision tree in this analysis, and Figures 24 – 26 were generated using the software. First, the probability of achieving the optimistic scenario was varied to see if the decision would change at certain values. Figure 21 shows that the North America option is favored in

every case (i.e., the decision does not change for the entire range of scenarios from optimistic to pessimistic):

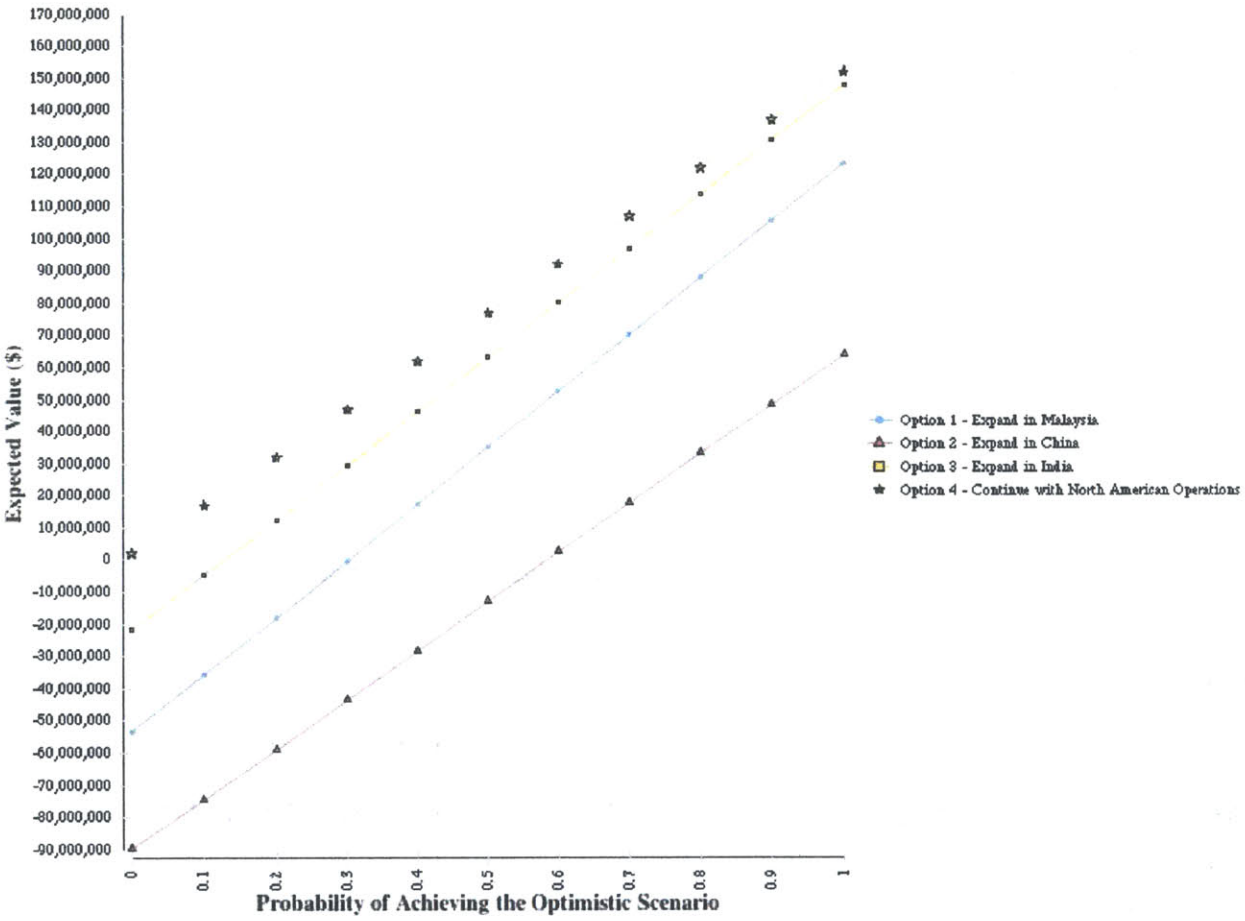


Figure 21 - Expected Value of All Options Versus Changes in the Scenario

In this case, the pessimistic and optimistic scenario probabilities are inversely proportional (e.g., if probability of the optimistic scenario =1, the probability of the pessimistic scenario = 0). Under the optimistic scenario, the total demand and revenues for Product Line B are higher. Consequently, if a failure were to occur within the existing North American operations in this scenario, the revenue loss would be higher. This is why the expected values of the Asia-Pacific options increase as the probability of the optimistic scenario increases. However, with the probabilities confirmed by the Supply Chain Strategy Group, the North America option has the highest outcome in every scenario.

On the other hand, the decision will change as the probability of a failure increases as evidenced in Figure 22 below:

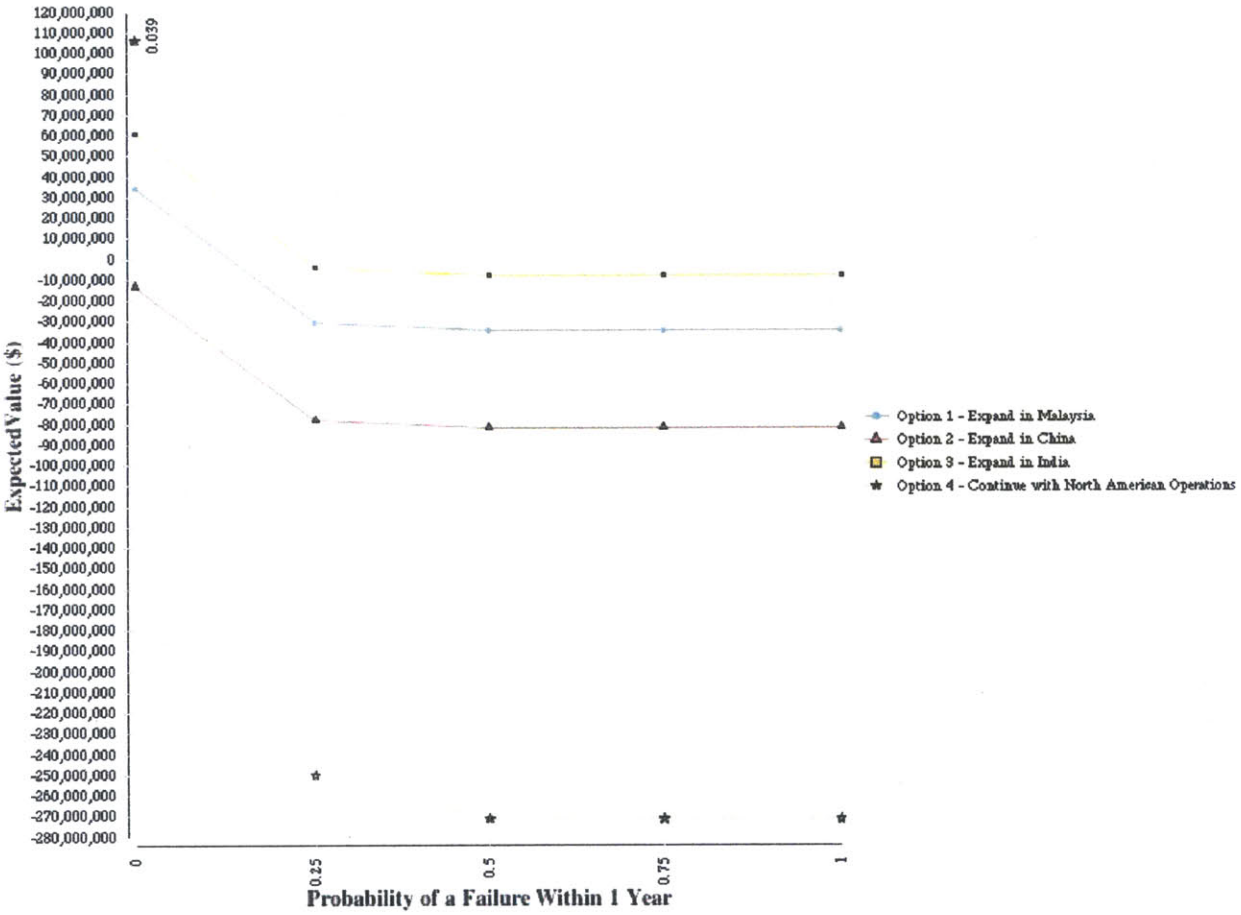


Figure 22 - Expected Value of All Options Versus the Changing Failure Probability (Within 1 Year)

We see that an increase in the probability of any type of failure from 1% per year to 3.9% per year (i.e., nearly four times greater) will change the decision in favor of the India option This is because expected revenue loss over the time horizon increases as the probability of a failure increases. In fact, if the probability of any type of failure were to reach 12%, all of the Asia-Pacific options would have higher outcomes than the North America option.

Further investigation into the type of failure (major and minor) versus to the probability of any failure occurring over a ten-year horizon was also conducted. Figure 23 shows how the decision changes

when both factors are varied (note: major and minor failures are inversely proportional in this case, i.e., the probability of a major failure = 0 means that the probability of a minor failure =1):

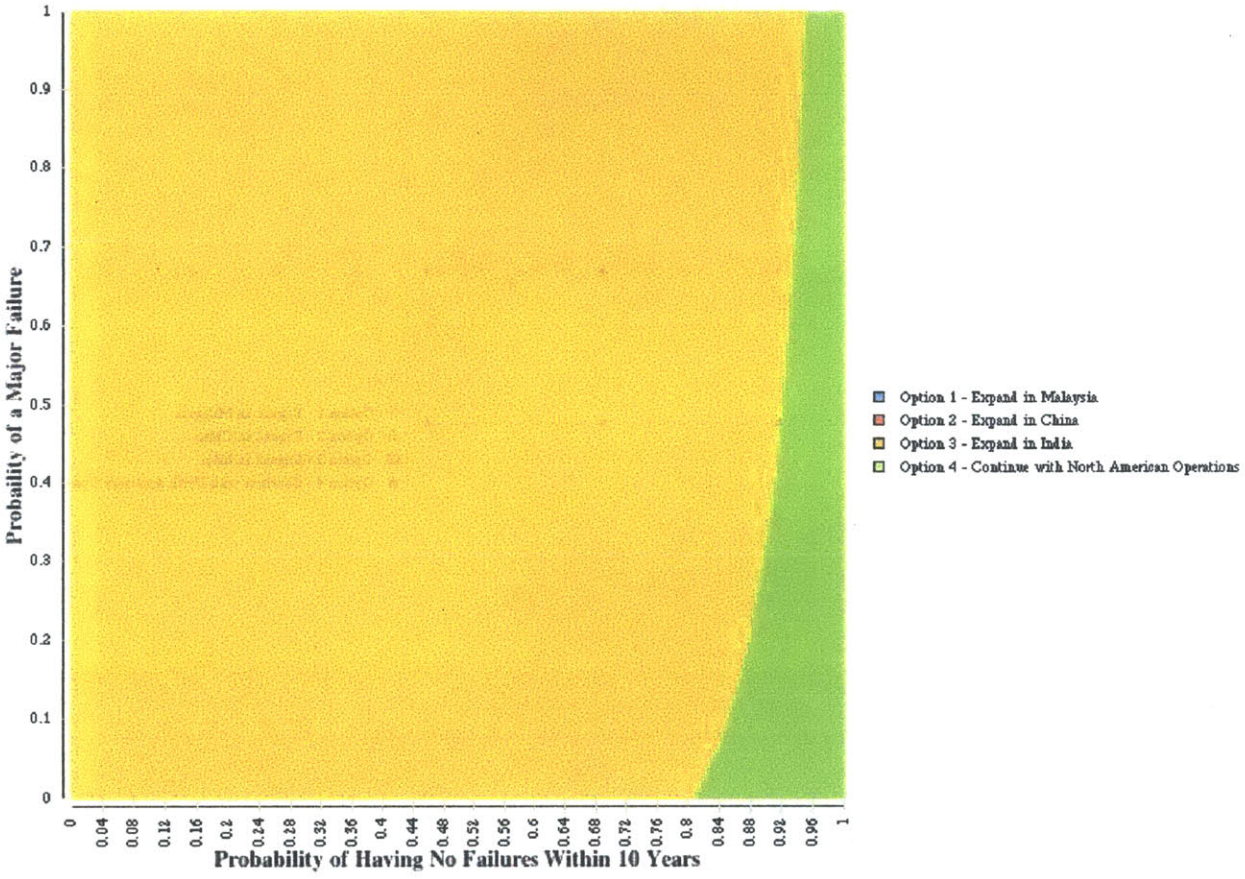


Figure 23 - Two-Way Sensitivity Analysis of the Failure Probability & Type

A key takeaway from this analysis is that the decision will change when the probability of a major failure in the current operations within ten years falls below 80%. In addition, the probability of not having a single failure (minor or major) within ten years must be greater than 95% in order for the North America option to be recommended versus any of the other expansion options. This is because any potential supply chain disruption in the current North American operations will result in a revenue loss large enough to change the outcome in favor of a dual sourcing option (expanding in India in this case).

Reviewing the overall results for the sensitivity analysis, it is clear that an increased probability of failure will likely favor an expansion option, which would allow for dual sourcing of Product Line B, over continuing current operations in North America with an additional shift (i.e., continuing to single-source Product Line B). This is due to the fact that the potential revenue loss as a result of a failure is large enough in every scenario (optimistic, realistic, and pessimistic) to change the expected outcome.

7 Further Considerations & Conclusion

This chapter presents a set of further considerations and concluding remarks based on the thesis research conducted and the case study. Reviewing the results presented in Chapter 6.4, it is advisable for the Supply Chain Group to continue sourcing SKUs of Product Line B from North America rather than expand its manufacturing operations to the Asia-Pacific region. However, this decision would be worth revisiting if certain factors were to change, specifically an increase in sales beyond the forecast or the ability to reduce import duties, as confirmed by the sensitivity analysis presented in Chapter 6.5. This chapter discusses the benefits of applying the methodology on other product lines and the considerations that would need to be reviewed further with a new product line that is not already being manufactured at the commercial scale.

Even though the results were not favorable towards regional expansion for the subsidiary evaluated, there may be other subsidiaries at Company X that could benefit from expanding manufacturing operations in the region. In addition, other opportunities were identified that could help both Company X and other medical device manufacturers in developing their manufacturing footprint strategies.

7.1 Considerations Beyond the Decision Analysis Results & the Case Study

It is important to consider various factors that were not included in the quantitative decision analysis for Product Line B. The following three examples, which were taken from the case study, highlight the importance of these factors when making the final decision(s) with respect to a footprint expansion:

1. Even though the India option has the highest NPV of all the expansion options evaluated, including Process Technology A as part of the facility's process capabilities could be considered

a risk based on the country's ability to protect trade secrets (Global Intellectual Property Center, 2012).

2. The India option will not allow for the addition of product lines beyond Product Line B due to space constraints in the existing facility. In the future, if additional product lines were selected as candidates for manufacturing in India (i.e., beyond those evaluated as part of the case study) then a new production facility would need to be constructed in order to do so.
3. Countries in the Asia-Pacific region could adopt a similar policy as Russia has done and require some level of domestic production in order to sell those products within the country in the future. If this were to happen in a major growth market (e.g., China), operational and project costs will become insignificant compared to the lost revenue if the domestic production requirement is not met.

A business process team will need to evaluate these risks in order to make the best decision possible. The Supply Chain Strategy Group currently does not currently have a regular, disciplined process with a well-managed cycle. However, once such a process is established, evaluating these issues on a regular basis will become much easier. The evaluation would take less time overall, and the data gathered could be refreshed quarterly instead of being recollected at a later point in time.

Although the decision analyses for the case study suggested that expansion was not as cost-effective as the North America option, expansion of manufacturing operations could be warranted for other subsidiaries. In fact, it is possible that the manufacturing of a combination of other product lines in a certain location may be more cost-effective than the current operations that include shipping products assembled in another region. Other product lines, beyond those that were assessed as part of this case study, must be evaluated using the methodology presented in order to determine whether such an opportunity exists. Further evaluations using the methodology will help to verify the generality and the applicability to other types of medical devices. On a similar note, it would be worthwhile to test the methodology on a new product line that the Supply Chain Group has not manufactured before.

The case study detailed in Chapter 6 illustrates how the methodology can be applied to an existing product line that is currently being manufactured in another region. However, this methodology is also applicable to a product line that is not currently manufactured within the company's network. The criteria for each phase ("What", "Where", and "How") would still need to be evaluated in the same fashion. In addition, infrastructure decisions would be very similar to the options presented in the case study (e.g., building a "greenfield" site in Malaysia, building a new facility at an existing site in China, and retrofitting an existing space within an existing facility in India). However, there are three factors that will require further consideration.

First, the evaluation of Process Maturity in the "What" phase will be difficult due to the fact that is a new product line and there is no commercial production experience. The business process team will need to rely on manufacturing performance at the clinical trial scale to determine if the new product line can be successfully manufactured with minimal issues. Second, there is an opportunity to change the procurement strategy (criteria for the "Where" and "How" phases). The External Operations Group generally prefers to use the suppliers that were contracted for clinical trial production rather than switching suppliers, but other medical device manufacturers may be willing to change suppliers in order to meet their commercial needs. Lastly, there will be scale-up considerations involving modifications required to produce at the commercial scale that are not applicable at the clinical scale in most circumstances. This will be part of the Operations & Technology Development evaluation in the "How" phase. Since this is a new commercial product line, there are no pre-existing product registrations, and process modifications can be made more easily as a result. As part of the business process, the Subsidiary Operations Development team member will have the most input for both of these considerations since they have direct ties to subsidiary R&D.

7.2 Other Opportunities Relating to Manufacturing Footprint Strategy Development

In completing this research with Company X, a number of other opportunities were identified that complement the development of the company's manufacturing footprint strategy in many ways. The identified opportunities are as follows:

1. Developing a procurement strategy for the Asia-Pacific region

   The evaluation of the subsidiary as part of the case study helped in realizing the financial and operational importance that suppliers have for the subsidiary evaluated (e.g., material costs account for 53% to 70% of total landed costs, depending on the location and the scenario). Moreover, some of the key suppliers do not have a manufacturing presence in the Asia-Pacific region. If the Supply Chain Group intends to further develop its internal and external manufacturing capabilities in the Asia-Pacific region in general, it must try to convince existing suppliers to establish a manufacturing presence in the region or it must identify new suppliers to meet its manufacturing needs. In addition to the increased responsiveness to the Manufacturing Group's raw material needs, there is the opportunity of reducing the expected import duty costs by complying with free trade agreements, many of which require local or regional sourcing. There are three hurdles that cannot be ignored when developing such a procurement strategy – the resources needed to qualify the new suppliers (cost, time, etc.), ensuring raw material quality with new suppliers, and maintaining strong relationships with existing suppliers.

2. Optimizing the current global manufacturing network

   When reviewing a number of subsidiaries prior to conducting the case study, it became apparent that certain subsidiaries had far more manufacturing facilities than others within the network of

the Supply Chain Group. For the supply chains of these subsidiaries, optimizing the current manufacturing networks prior to making footprint decisions could result in certain expansion options no longer being required. These network optimizations would be completed prior to starting the "Where" phase of the methodology once the product is considered a suitable candidate as part of the "What" phase. If an opportunity exists but is considered comparable with the potential expansion options in the Asia-Pacific region by the business process team, the option should be evaluated with the decision analysis tools to determine the best path forward (e.g., whether it is more cost-effective or beneficial to optimize the network or move forward with a footprint expansion). Similar to the updates as part of the business process cycle, any significant changes that are discovered during the quarterly or semiannual updates should be reviewed for both the expansion and optimization options (assuming that neither is initially selected as evidenced in the case study presented in Chapter 6).

3. Enhancing the current decision analysis tools

As previously mentioned, the NPV analysis used by the Finance Group at Company X does not account for certain data that was included as part of the total landed cost analysis (e.g., outbound freight, estimated import taxes and duties). Both the Finance and Supply Chain Strategy Groups should consider the possibility of accounting for these costs as part of their standard NPV analysis. If it becomes difficult to do so, it would be worthwhile for both groups to develop a standardized approach to the total landed cost analysis, similar to what was completed in this thesis research, so that the data and their respective uncertainties will be evaluated as part of the decision making process. In addition, many companies such as Company X have typically evaluated options under one set of uncertainties. It is important to understand the range of outcomes and potential influences rather than anchoring on a single value. These companies could standardize a way of determining this range (e.g., simulation, scenario analysis). It will help

in understanding the overall risks associated with the various options, which in turn will allow a team to make the best decision based on the different options.

7.3 Conclusion

This thesis offers a comprehensive, broadly applicable methodology and a rigorous business process to aid medical device manufacturers in the evaluation of their Asia-Pacific manufacturing footprint strategies. A case study was also presented in which the methodology was applied to a specific subsidiary at Company X. Though the decision analysis results suggested that it is more cost-effective for the Supply Chain Group to continue shipping SKUs of Product Line B from North America to the region rather than expand its manufacturing operations, the decision criteria should be reviewed regularly in order to keep abreast of the changing economic, government, and regulatory landscapes. These factors will be different when dealing with new product lines, but the same methodology can still be applied.

Senior leaders across Company X have consistently highlighted the importance of the Asia Pacific region, especially the emerging markets, in their medical device long-term growth strategy. The methodology and the business process presented will allow the company, as well as other medical device manufacturers, to meet those future needs and be confident that they have made the right decision the first time.

Appendix A: Formulas & Risk Factors Applied

This section outlines all of the risk factors and equations used for the analysis of the subsidiary as detailed in Chapter 6. Although these equations were developed and applied for Company X, they are potentially applicable for other manufacturers as well. Each section of this appendix highlights the equations that were applied as part of the total landed cost analysis and the NPV analysis. Company X considers the calculations for the NPV analysis and data inputs for the equations (e.g., scaling factors, costs, weights) as proprietary information. For this reason, details of the associated calculations are not discussed in-depth. The last section provides an overview of all of the uncertainties used in the three scenarios as well as the sources for that data. The following is a list of general items that apply to each section:

- Many of the data points are dependent on the applicable year. The term "t" represents the year for that data point. 2013 is represented as t = 0, and t increases incrementally by year (e.g., 2014, t=1).
- Unless otherwise stated, all costs are in U.S. dollars. This is because a majority of the transactions are completed in the U.S. with international brokers. This was confirmed with the groups that handle these expenses as part of the analysis with Company X.
- Currency fluctuations are very difficult to predict over long periods of time and are dependent on a variety of factors (interest rates, exports, etc.). For the case study completed with Company X, it was assumed that the valuation would generally increase or decrease over a long period of time. The term "currency depreciation" refers to this expected currency change over time. If the value is negative, it means that the local foreign currency will appreciate versus the U.S. dollar for that period. Tables 11 and 12 includes the values and sources that were determined as part of the analysis. Various companies may use tactics to hedge against currency fluctuations and avoid these additional costs.

- Various inflation factors are described in this appendix. Unless otherwise stated, nominal inflation is defined by the following equation:

$$Nominal\ Inflation = Real\ Inflation + Price\ Inflation$$

  Price inflation is dependent on the type of cost and where the transaction takes place. This is specified in each section where the formula is applicable.

The relevant equations and reasoning are separated into the following sections in this appendix: Revenue, Demand, Weight and Volume, Material Costs, Labor Costs (Direct and Indirect), Additional Overhead Costs, Transportation Costs, Costs for Import Duties and Associated Taxes, and Inventory Holding Costs.

Revenue

The current revenues for each product line and their annual growth rates must be given in order to determine the future revenues. The growth rates can be modified using the following equation:

$$sales\ growth\ rate(t) = E[growth\ rate(t)] \times F$$

"F" is the scaling factor for modifying the growth rate for each of the scenarios, and "E[growth rate(t)]" is the given annual growth rate. As an example to show the equation works, if the sales growth rate is expected to be 50% of the expected growth rate for a certain scenario, all of the values are shifted lower by 50% of the expected value (i.e., 2% growth rate will become 1%, and a -4% growth rate will become -6%). Using the modified growth rate, the following equation is then applied to determine the revenue for each year:

$$Revenue(t) = Revenue(t-1) \times [1 + sales\ growth\ rate(t)]$$

Revenues for the case study described in Chapter 6 were stated in U.S. dollars, so no modifications were required. Both equations listed above can be applied to the Global and Asia-Pacific (APAC) revenue data as needed.

Demand

This analysis required the current demand volumes to be calculated for the various product lines. Working with the Production Planning Group, which is part of the Supply Chain Group, it was discovered that the demand growth rates were not equal to the sales growth rates due to pricing changes and product cannibalization (i.e., certain SKUs would replace the sale of others). The following equation can be applied:

$$demand\ growth\ rate(t) = sales\ growth\ rate(t) \times X$$

"X" is the scaling factor to account for the expected inequality. To determine this factor for Product Line B, previous demand volumes were compared to the revenues from 2009 to 2011 Similarly to determining the yearly revenues, the demand volumes can be calculated using the following equation:

$$Demand(t) = Demand(t-1) \times [1 + demand\ growth\ rate(t)]$$

Demand, in this case, is the number of boxes for the product line analyzed. For the product lines evaluated as part of the case study, certain breakdowns were required between different products within a product line (e.g., surgical instruments and consumable components for Product Line B). Historical data for sales and demand volume between 2009 and 2011 was analyzed to determine the projected breakdown for those product lines. At Company X, the demand data was only given as global demand. Therefore, the data needed to be translated to the regional demand for APAC. To do that, further evaluation was completed of previous APAC and global demand volumes, and a relationship was found based on the APAC revenue percentage. The following equation illustrates this relationship:

$$APAC\ Demand(t) = P \times \frac{APAC\ Revenue(t)}{Global\ Revenue(t)} \times Global\ Demand(t)$$

"P" is the scaling factor that was applied to determine the APAC demand. If P < 1, it means that there is a pricing difference that generates less demand volume in APAC (vice-versa if P > 1).

These demand volumes did not initially include any inventory changes. The following equation can be used to determine the change in inventory for each year:

$$\Delta\ APAC\ Inventory(t) = T \times [APAC\ Demand(t) - APAC\ Demand(t-1)]$$

"T" is the expected inventory supply in terms of years. Generally speaking, Company X tries to maintain one month's supply of Product Line B in finished goods inventory. Total demand for the APAC region in a given year can then be determined using the following equation:

$$Total\ Demand(t) = APAC\ Demand(t) + \Delta\ APAC\ Inventory(t)$$

As mentioned before, the analysis discussed in Chapter 6 only accounted for demand in the APAC region and thus equals to the total demand satisfied by the new location.

Weight & Volume

Weight and Volume are required to estimate the sterilization and shipping costs. Data for the actual weight (lb.) and volume (in^3) for each SKU of Product Line B was analyzed to determine the overall weighted average that can be used for the calculations. Due to transportation requirements, the dimensional weight needed to be calculated first using the following equation:

$$Unit\ Dimensional\ Weight(t) = \frac{Unit\ Actual\ Weight(t)}{166\ \frac{in^3}{lb}} \times \frac{1\ kg}{2.205\ lb} \times Z$$

"Z" is a scaling factor applied to account for the space needed for transportation packaging. The number 166 represents the expected volume-to-weight ratio that would be applied to determine the dimensional weight. The Transportation Group confirmed that the transportation costs would be highest between the dimensional and actual weights as shown in the following equation:

$$Unit\ Chargeable\ Weight(t) = MAX[Unit\ Dimensional\ Weight(t), Unit\ Actual\ Weight(t)]$$

For every SKU in Product Line B, the dimensional weight equaled the chargeable weight. This was not always the case for the other product lines evaluated. Using the chargeable weight, the total weight that would be charged for transportation was determined with the following equation:

$$Total\ Weight(t) = Unit\ Chargeable\ Weight(t) \times Total\ Demand(t)$$

In a similar fashion, the volume required for sterilization can be determined using the following equation:

$$Sterilizeable\ Volume(t) = Unit\ Dimensional\ Weight(t) \times Total\ Demand(t) \times S$$

"S" is a scaling factor used to represent the additional volume taken up by the "tote" (i.e., set of boxes for sterilization). These totes increase the sterilizable volume beyond that required for the packaged devices themselves.

Material Costs

To determine the material costs for each year, we need to understand what the expected material costs will be per unit of demand. For the analysis, the weighted average of the material costs for each SKU was determine through available cost accounting data from the Finance Group. The following equation cab then be applied:

$$Total\ Material\ Costs(t) = E[Material\ Cost] \times Total\ Demand(t) \times [1 + material\ cost\ growth\ rate]^t$$

The "material cost growth rate" is a risk factor that accounts for the potential increase or decrease in material costs over time. Material costs could increase due to price inflation or scarcity of materials, but they could also decrease due to price competition. Table 11 in this section includes the anticipated growth rate in each of the scenarios. For all locations, the material costs were anticipated to be the same. However, raw material transportation costs will differ depending on the manufacturing location being evaluated.

Labor Costs (Direct & Indirect)

Both direct and indirect labor costs can be calculated using the following equation:

$$Labor\ Cost(t) = Labor\ Number(t) \times Avg.Salary \times [1 + nominal\ wage\ inflation]^t \times [1 - currency\ depreciation]^t$$

"Labor Number" represents the expected number of operators or employees for the year. For the analysis, labor costs were variable based on the production volume. However, they do not increase at the same rate. Furthermore, indirect labor costs are considered an overhead cost at Company C. The Finance Group maintains the average salary calculations for both direct and indirect labor. In addition, the company maintains its own estimates for real wage inflation as well as country-specific inflation per Table. For the landed cost calculations specific to the current operations in North America, real wage inflation was assumed to be negligible based on input from the Finance Group. The labor costs would also be affected by currency appreciation or depreciation at each location since payments would be made in the local currencies as opposed to U.S. Dollars.

Additional Overhead Costs

There are five components in the total overhead costs that were analyzed: indirect labor, inbound / in-transit transportation, depreciation, sterilization costs, and additional manufacturing burden. The Finance Group at Company X considers these components as overhead expenses, and all of the overhead costs in this case are variable except for the depreciation. Details for indirect labor and inbound / in-transit transportation costs are respectively given in the "Labor Costs" and "Transportation Costs" sections of this appendix.

To account for the depreciation costs as part of the landed cost analysis, the expected depreciation amount was calculated using a 10-year straight-line assumption. The value was based primarily on the equipment and machinery costs. For the NPV analysis completed by the Finance Group, a different method was used to calculate the depreciation expenses. Depreciation is not affected by inflation or currency depreciation in this type of analysis.

To determine the total sterilization costs, the following equation can be used:

$$Total\ Sterilization\ Costs(t) = Sterilizeable\ Volume(t) \times Sterilization\ Cost$$

Sterilization Cost is a pre-negotiated price that Company X has established with various sterilization contractors. Factors that influence this price include lead-time requirements, expected volumes for sterilization, and market competition. For the case study, the sterilization cost was assumed to be a constant value based on the information provided by the External Operations Group.

Additional manufacturing burden (a variable overhead cost) accounts for all of the other factors affecting overhead (e.g., utilities, lubrication, maintenance), and they are subject to both price inflation and currency depreciation. The Finance Group keeps track of these costs on a regular basis. The following equation can be applied based to calculate the year-over-year costs:

$$Add'l\ Mfg\ Burden(t)$$

$$= Add'l\ Mfg\ Burden(t-1) \times [1 + price\ inflation] \times [1 - currency\ depreciation]$$

"Price inflation" is dependent on the manufacturing location and is a risk factor that varies in each scenario. Table 11 in this appendix provides the values that were used as part of the case study.

Transportation Costs

Since manufacturers will have different expectations regarding transportation (e.g., modes, lead times), this section shows how the costs were calculated within the Transportation Group at Company X. Although the Finance Group considers inbound / in-transit transportation to be part of the overhead costs, outbound transportation costs are not part of the overhead costs for the product lines analyzed.

A combination of airfreight and truck shipping are used for moving finished goods, work-in-progress parts, and raw materials associated with Product Line B along pre-determined lanes. As part of the analysis, transportation costs were found to be dependent on the weight or the number of shipments. To calculate the number of shipments, the following equation can be used:

$$Total\ Shipments(t) = \frac{Total\ Demand(t)}{B}$$

"B" represents the number of boxes that are carried in a shipment. It is important to note that shipment sizes in the U.S. differed from those in APAC due to different truck and carton sizes (i.e., different values for "B" were applied in each situation).

The next step is to determine the expected freight inflation for both methods of transportation (note: fuel inflation is separate from freight inflation). Based on the data provided by the Transportation Group, real freight inflation did not change over long periods of time (2-3 year periods). Therefore, freight was assumed to only be dependent on country-specific price inflation. Since the costs are in U.S. dollars, the

inflation growth rate was equal to the expected U.S. inflation for each scenario. On the other hand, fuel inflation was expected to change over time. The following equation can be applied to determine the total airfreight costs:

$$Total\ Airfreight\ Costs(t) = \left\{\left[\left(\sum_i Weight\ Based\ Costs(i) - Fuel\ Costs\right) \times Total\ Weight(t)\right] + \left[\left(\sum_i Shipment\ Based\ Costs(i)\right) \times Total\ Shipments(t)\right]\right\} \times [1 + price\ inflation]^t + (Fuel\ Costs \times [1 + nominal\ oil\ price\ growth\ rate]^t)$$

Weight-base costs, which are dependent on the weight of the products being shipped, include the following (represented by *i*): airfreight, security, x-ray, pick-up, handling, transfers, and delivery. Fuel costs are also considered a weight-based cost, but they will also increase by the real growth rate of fuel prices. The Transportation Group confirmed that the real growth rate of fuel prices is approximately equal to the real growth rate of oil prices. Thus, the nominal oil price growth rate, which is the real oil price growth rate plus the U.S. inflation rate, was applied to the fuel costs. Table 11 includes the real growth rate of oil prices for each scenario. Shipment-based costs, which are dependent on the number of shipments and are also represented by *i*, include document handling, document clearing, and broker fees. For truck-based shipping, fuel costs cannot be separated from other costs. In addition, the costs are based solely on the number of shipments as opposed to weight. In light of this information, the following equation should be applied to determine the total inflation for truck-based shipments:

$$modified\ freight\ inflation = (60\% \times price\ inflation) + (40\% \times nominal\ oil\ inflation)$$

Experts in the Transportation Group at Company X confirmed these percentages (60% and 40%). As mentioned before, since real freight inflation did not change over time, the expected U.S. inflation rate was used. The total shipping costs for truck freight can be determined with the following equation:

$$Total\ Truck\ Shipping\ Costs(t)$$

$$= Total\ Shipments\ (t) \times \frac{Truck\ Costs}{Shipment} \times [1 + modified\ freight\ inflation]^t$$

Since the primary modes of transportation are air and truck, the following equation can then be used to determine the total transportation costs for an identified lane.

$$Total\ Transportation\ Costs(t) = Total\ Airfreight\ Costs(t) + Total\ Truck\ Shipping\ Costs(t)$$

This equation can be directly applied for the outbound and in-transit lanes to determine those transportation costs. If another medical device manufacturer did use ocean freight as a means of transportation, those costs would also need to factor in the "Total Transportation Costs(t)" equation.

As part of this analysis, assumptions were made for each scenario regarding the possibility of utilizing local sourcing or having current suppliers produce raw materials closer to the new manufacturing location. In either of those situations, the raw material transportation costs would change. The following equation can be used:

$$Total\ Raw\ Material\ Inbound\ Transportation\ Costs(t)$$

$$= R \times Total\ Inbound\ Transportation\ Costs(t)$$

"R" is the scalable factor for the anticipated inbound transportation costs. This is considered an uncertainty, and further details can be found in Tables 11 and 12. Inbound Transportation Costs can be separated into truck and airfreight as needed for other calculations such as raw material import duties and taxes.

Expected Costs for Import Duties & Associated Taxes

Import duties and taxes differ by country and by manufacturing location, and they can differ for the same country if certain criteria are met (e.g., meeting the procurement requirements for free trade agreements). For this reason, the demand volume needs to be identified by country or sub-region whenever possible. For the case study presented in this thesis, demand volumes were calculated for Japan, China, and India, which in total make up more than 50% of revenue in the region, based on the sales forecasts for each country using the formulas described earlier in this appendix. The remaining volume was designated as "Other APAC", and the duty and tax rates used to estimate the expected costs were taken as the average of the rates based on the guidance of the experts within the Transportation Group. The first step in determining the associated costs is to calculate the "Cost Plus Freight" value for each country. The following equation was developed and applied:

$$Finished\ Goods\ Cost\ Plus\ Freight(t) = \left(Standard\ Cost\ per\ Unit + \frac{Total\ Outbound\ Freight\ Costs}{\#\ of\ units}\right) \times Country\ Demand(t)$$

"Standard Cost per Unit" is the per-unit manufacturing cost (i.e., materials, labor, and overhead combined). For this analysis, outbound freight costs were simplified and considered equal to the freight costs from the manufacturing location to the regional distribution center in Singapore, where all products distributed by Company X throughout the APAC region are initially sent. This is a significant simplification that was made with the guidance of the Transportation Group for this analysis. The next step is to determine the associated duties and import taxes for each location. It is important to note that certain locations may have import duties but no additional taxes or other fees and vice-versa. For the case study presented in this thesis, the Transportation Group was able to provide this information based on the Harmonized System Code for Product Line B. The associated costs can then be calculated using the equation below:

$$Total\ Finished\ Goods\ Import\ Duties\ \&\ Taxes(t)$$

$$= \sum_i Finished\ Goods\ Cost\ Plus\ Freight(i,t) \times (Duty(i) + Import\ Tax(i) + Other\ Fees(i))$$

The term "i" represents each country or sub-region where products are being distributed. For this analysis, the rates for the duties, import taxes, and additional fees depended on whether or not Company X was able to meet free trade agreements for the specific location. If so, the rates are much lower. The Transportation Group was not confident that free trade agreements could be easily met due to the current raw material procurement strategy for Product Line B. Consequently, the scenario for free trade agreements being satisfied was only applicable in the optimistic scenario. The rates can also change without ample notice, but this was not applied in the analysis. However, this is something that the Supply Chain Strategy Group at Company X should monitor as part of the business process.

Import duties and associated taxes for raw materials were calculated in a similar manner. First, the "Cost Plus Freight" for the raw materials needs to be determined using the following equation:

$$Raw\ Materials\ Cost\ Plus\ Freight(t)$$

$$= (Total\ Material\ Costs(t) \times R) + Total\ Raw\ Material\ Inbound\ Airfreight\ Costs(t)$$

Only imported materials are subject to duties and taxes, hence the need for the scalable factor "R" (defined in the "Transportation Costs" section). For the analysis, since truck shipping costs were minimal in comparison to the airfreight costs at each of the manufacturing locations, they were not included. If they were more significant, they would need to be included as well.

$$Total\ Raw\ Materials\ Import\ Duties\ \&\ Taxes(t)$$

$$= Raw\ Materials\ Cost\ Plus\ Freight(t) \times (Duty(i) + Import\ Tax(i) + Other\ Fees(i))$$

The term "i" refers to the manufacturing location. In this analysis, the Transportation Group confirmed that there were no immediate rate changes even if free trade agreements were satisfied in Malaysia,

China, and India. Of the three countries in the APAC region chosen for further evaluation, Malaysia is the only country of the three evaluated that does not charge any import duties or taxes on raw materials for medical device manufacturers This analysis assumes that the requirements for Pioneer Status are met (Ernst & Young, 2012). The Transportation Group also confirmed that there are no raw material import duties and taxes for the North American operations based on existing agreements.

Inventory Carrying Costs

The inventory carrying costs must be included in the decision analysis, and these costs should be applied for raw materials, work-in-progress goods, and finished goods. The carrying costs include the inventory holding costs and cost of financing as defined by Simchi-Levi (2008). For the case study with Product Line B, the work-in-progress inventory was not accounted for due to the relatively short time needed for the assembly process (i.e., 1 day). In addition, since sterilization costs did not have a significant impact on COGS and the transit time was relatively short (i.e., 1-2 days), the standard cost per unit was applied. The following equation can be used to calculate the total inventory carrying costs

$$Inventory\ Carrying\ Cost(t) = [(Raw\ Material\ Costs(t) \times M) + (Standard\ Cost\ per\ Unit \times Total\ Demand(t) \times L)] \times c$$

"M" is the length of time that raw materials are held prior to assembly, and "L" is the lead time from the end of mechanical assembly to the arrival at the regional distribution center in Singapore. Both of these values were measured in days but converted to years for the calculations. The term "c" is the inventory carrying cost, and this value was ascertained from the Finance Group in Company X as a general estimate. The Finance Group assumed that the carrying costs would be the same regardless of the manufacturing location.

Risk Factors

Table 11 includes all of the risk factors and uncertainties applied for each scenario and each manufacturing location in this analysis. Table 12 provides the sources and respective notes for the chosen risk factors and uncertainties.

Table 11 - Risk Factors & Uncertainties for Each Location & Scenario

	Malaysia			China			India			North America (Current)		
	Optimistic	*Realistic*	*Pessimistic*	*Optimistic*	*Realistic*	*Pessimistic*	*Optimistic*	*Realistic*	*Pessimistic*	*Optimistic*	*Realistic*	*Pessimistic*
Asia-Pacific Sales Forecast (regional- & country-specific)	100.00%	75.00%	50.00%	100.00%	75.00%	50.00%	100.00%	75.00%	50.00%	100.00%	75.00%	50.00%
Price Inflation (country-specific)	1.21%	1.80%	2.39%	2.08%	3.10%	4.12%	5.90%	8.80%	11.70%	*equal to the U.S. Inflation Rate listed further below		
Fuel Price Inflation (real)	-0.98%	2.44%	3.76%	-0.98%	2.44%	3.76%	-0.98%	2.44%	3.76%	-0.98%	2.44%	3.76%
Wage Inflation (real)	0.47%	0.70%	0.93%	7.17%	10.70%	14.23%	0.74%	1.10%	1.46%	N/A (assumed no real wage inflation in the U.S.)		
Currency Appreciation / Depreciation	-0.66%	-1.27%	-4.89%	-2.77%	-3.37%	-4.13%	2.51%	0.24%	-3.09%	N/A (all prices in U.S. dollars)		
Project Cost Factor	90.00%	100.00%	120.00%	90.00%	100.00%	120.00%	90.00%	100.00%	120.00%	N/A (no additional project required)		
Material Cost Factor	99.00%	100.00%	102.00%	99.00%	100.00%	102.00%	99.00%	100.00%	102.00%	99.00%	100.00%	102.00%
U.S.Price Inflation	1.63%	2.80%	3.60%	1.63%	2.80%	3.60%	1.63%	2.80%	3.60%	1.63%	2.80%	3.60%
Materials Freight Change Factor	50%	75%	100%	50%	75%	100%	50%	75%	100%	N/A (no changes anticipated for current material freight)		
Project Timeline (years)	3.0	3.5	4.0	4.0	4.5	5.0	3.0	3.5	4.0	N/A (no capital project required)		
Import Taxes & Duties Scenario	Free trade agreements in place	No free trade agreements in place	No free trade agreements in place	Free trade agreements in place	No free trade agreements in place	No free trade agreements in place	Free trade agreements in place	No free trade agreements in place	No free trade agreements in place	Free trade agreements in place	No free trade agreements in place	No free trade agreements in place

Table 12 - Sources & Notes for the Chosen Risk Factors & Uncertainties

	Source	Notes
Asia-Pacific Sales Forecast (regional & country-specific)	Company X - discussions with Finance and Commercial Groups	*Defined as scalable factor "F" *100% = hit sales forecast as expected, 75% = hit sales forecast by 75%, 50% = hit sales forecast by 50% [note: general expectation are that the sales forecast is only met by 75%] *Sales forecasts already assume inflation, exchange rate fluctuations, etc. (i.e., no modifications required)
Price Inflation (country-specific)	Company X - economic research provided to the Commercial Groups	*Taken as the 67%, 100%, and 133% (optimistic, realistic, and pessimistic respectively) for each country based on the report
Fuel Price Inflation (Real)	(U.S. Energy Information Administration, 2012)	*Based on the best-case, realistic, and worst-case scenarios as evaluated from 2010 - 2035
Wage Inflation (Real)	Company X - economic research provided to the Commercial Groups	*Taken as the 67%, 100%, and 133% (optimistic, realistic, and pessimistic respectively) for each country based on the report
Currency Appreciation / Depreciation	(XE Currency Tables, 2012)	*Looked at exchange rate data from 2004 - Dec 2012 and calculated the 33rd (optimistic), 50th (realistic), and 67th (pessimistic) percentiles of annual values
Project Cost Factor	Company X- discussion with the Manufacturing and Manufacturing Engineering Groups	* -10% / +20% (optimisitic and pessimistic respectively) of the calculated project costs in Chapter 6
Material Cost Factor	Company X - discussion with the External Supply and Production Planning Groups	*1% decrease per year in material costs (optimistic) and a 2% increase (pessimistic) assumed based ont eh reason discussed in this Appendix ("Material Costs" Section)
U.S. Price Inflation	(Coin News Media Group, 2012)	*33rd (optimistic), 50th (realistic), and 67th (pessimistic) percentiles of US price inflation from 1926 - 2011
Materials Freight Change Factor	Company X - discussion with the Production Planning Group	*Assume material freight costs decrease by 50% (optimistic), by 25% (realistic), and 0% (pessimistic) when establishing the Asia-Pac location; *This is due to finding local suppliers or having current suppliers source from APAC locations
Project Timeline (years)	Company X - discussion with the Supply Chain Strategy Group and the subsidiary R&D	*Assume additional year for China due to clinical trial requirements
Import Taxes & Duties Scenario	Company X - discussion with the Transportation Group	*Free trade agreements allow for reduced or no duties to be leveraged on product exported to that country *In order to satsify the agreeements, one must show that 65%-80% of raw materials are coming from APAC supplier (acutal percentage depends on the country)

Appendix B: Decision Analysis for Product Line B

This section includes discussions around the landed cost analysis, the NPV analysis, and the decision tree analysis in Chapter 6.4. I developed the templates and frameworks for both the total landed cost and the decision tree analyses. Company X required the use of their template for the NPV analysis. As mentioned before, the original data was modified to maintain confidentiality of proprietary information for Company X. Details for each analysis are included in the separate sections below.

Total Landed Cost Analysis

The results of the total landed cost analysis, including the breakdowns for the options for each scenario (optimistic, realistic, and pessimistic) cannot be revealed to further maintain confidentiality of proprietary information for Company X. Table 13 below shows the how the cost breakdowns were reviewed as part of this analysis:

Table 13 - Total Landed Cost Breakdown Reviewed in the Case Study

	Option (Malaysia, China, India, North America)		
	Optimistic	*Realistic*	*Pessimistic*
Material Costs			
Direct Labor Costs			
Overhead Costs			
Indirect Labor			
Inbound Freight			
Sterilization & Transit Freight			
Add'l Manufacturing Burden			
Expected Depreciation			
Outbound Freight			
Estimated Duties & Import Taxes			
Raw Material Import Taxes			
Finished Goods Duties & Import Taxes			
Total Inventory Carrying Costs			
Raw Materials Inventory			
Work-in-Progress & Finished Goods Inventory			
APAC Total Landed Costs			
Number of Boxes Produced / Shipped			
APAC Total Landed Cost per Box			
Breakdown per Box			
Materials			
Direct Labor			
Overhead (No Freight Included)			
Inbound & Outboud Freight			
Duties & Import Taxes			
Inventory Carrying Costs			
Percentage per Box			
Materials			
Direct Labor			
Overhead (No Freight Included)			
Inbound & Outboud Freight			
Duties & Import Taxes			
Inventory Carrying Costs			

All calculations were completed using the modified data set and the equations listed in Appendix A. Although import taxes and duties are actually paid when the product is shipped to a specific country, estimates were calculated based on the manufacturing location and the current rates paid by Company X. The total landed cost calculations for North America were made using the overhead values from the standard cost data, and detailed breakdowns for sterilization, in-transit freight, depreciation, and additional manufacturing burden were not available. The Finance Group at Company X provided the standard cost data used for this analysis.

NPV Analysis

As mentioned in Chapter 6.4, the NPV analysis was completed with help from the Finance Group at Company X. Both the Supply Chain Strategy and Finance Groups required the use of the company's NPV template as opposed to creating a separate template for this analysis. This allowed for the NPV results to be easily compared to other projects being evaluated by the groups at the time. On the other hand, this did not allow for modifications to projected revenues beyond a specified year. The following is a list of general highlights from the NPV analysis:

- The NPV analysis can be broken down into the following categories: incremental revenue, operating expenses (i.e., COGS, SG&A), project costs, and recurring costs (i.e., cost savings or increases as result of the production shift). Taxes are deducted from the subtotal, and the resulting annual cash flow is then discounted.
- The calculations are based on the yearly incremental sales in the region. Therefore, as long as the sum of the project costs, operating costs, and recurring costs are less than the cash flow generated from sales over the specified time horizon, the NPV value will be positive.
- The applied tax rate was determined after consulting with tax experts within the Finance Group. Although some of the locations evaluated provide tax incentives that could decrease the effective

rate, the experts noted that it could change the current tax structures in place, and they did not recommend any changes to the current structures.

- The Finance Group currently does not account for the following as part of its NPV analysis: outbound freight, import duties and taxes, and associated inventory costs. Consequently, they were not included. This made it difficult to determine what changes to uncertainties for these costs could result in a higher NPV for Malaysia or China versus India. This highlights the importance of using a variety of decision analysis tools, since another tool can be used to identify and account for these costs.

Further details regarding calculations and tax rates cannot be revealed in order to maintain confidentiality for Company X.

Decision Tree Analysis

Figures 24, 25, 26, and 27 show the branches of the decision tree for each option (note: the decision tree was created and analyzed using TreeAge™ Pro Software, and each figure is a screenshot from the program):

Figure 24 - Decision Tree Structure for the Malaysia Option

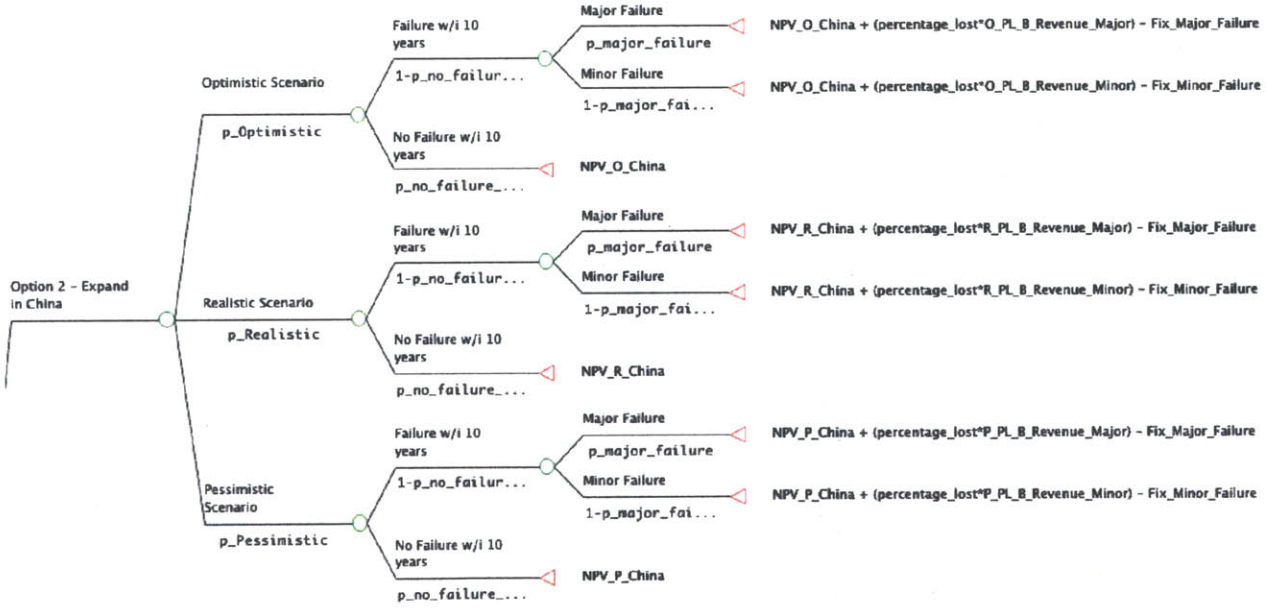


Figure 25 - Decision Tree Structure for the China Option

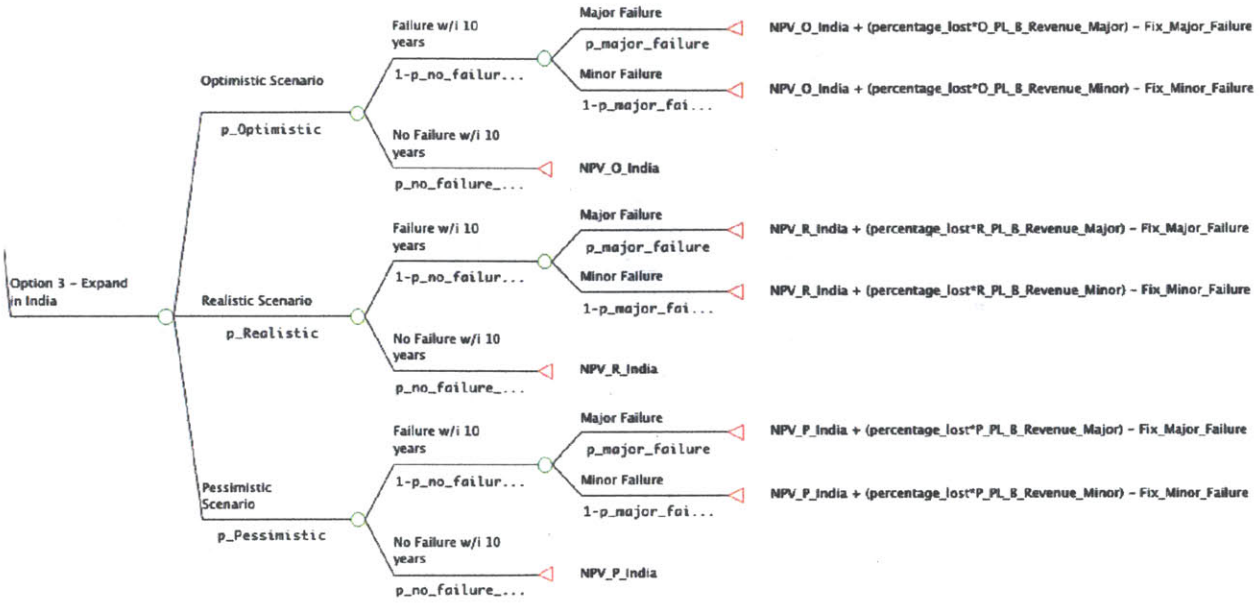


Figure 26 - Decision Tree Structure for the India Option

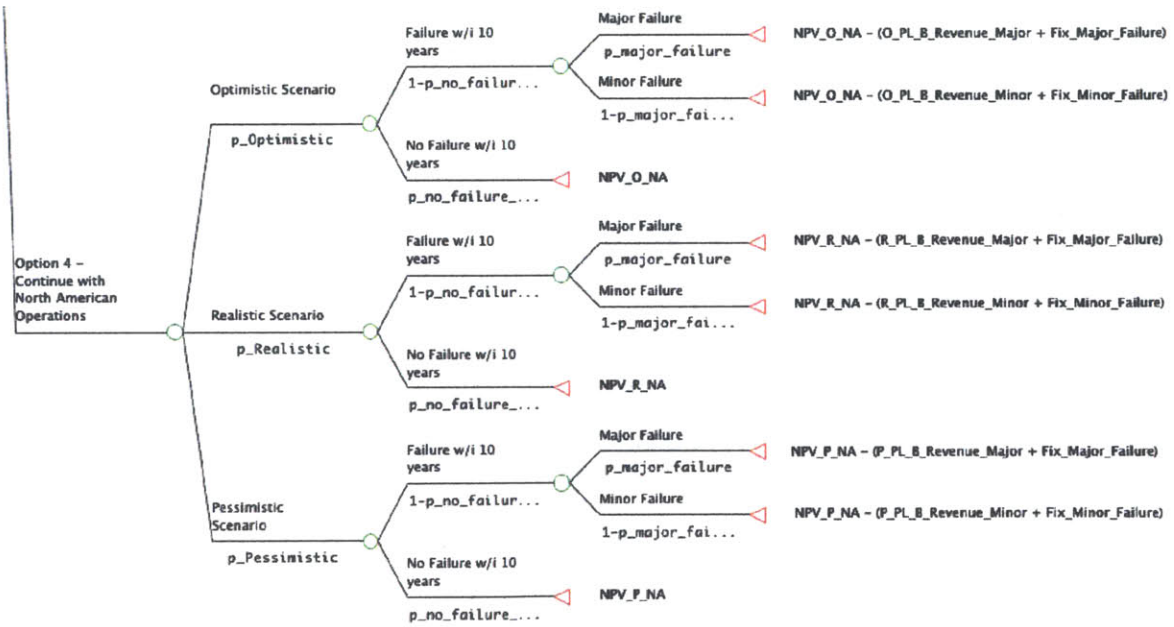


Figure 27 - Decision Tree Structure for the North America Option

For each option, the probability of each scenario (optimistic, realistic, and pessimistic) occurring was identified with help from the Supply Chain Strategy Group. Then, the probability of a single failure

occurring was calculated using the probability of an annual failure as well as the probability of that failure being a major or a minor failure. The Supply Chain Strategy Group was instrumental, once again, in providing these values for the analysis. If a failure did occur, the expected revenue loss and the cost to remedy that failure were subtracted from the NPV value, which differed based on the option and the scenario. As previously mentioned, the NPV values used were calculated with using the standards set by the Finance Group at Company X.

Table 14 below lists the variables and the probabilities that were used in the decision tree analysis:

Table 14 - Decision Tree Variables & Probabilities

Variable Name	Description	Value
p_Optimistic	Probability of the optimistic scenario	0.25
p_Realistic	Probability of the realistic scenario	0.50
p_Pessimistic	Probability of the pessimistic scenario	0.25
p_failure_in_year	Probability of a failure in 1 year	0.01
p_no_failure_10_years	Probability of no failures within 10 years	(1-p_failure_in_year)^10
p_major_failure	Probaility of a major failure i.e. 1 year revenue loss	0.1
p_minor_failure	Probability of a minor failure i.e. 3 months revenue loss	1-p_major_failure
NPV_O_China	China Optimistic NPV	71110634.83
NPV_R_China	China Realistic NPV	-20043369.46
NPV_P_China	China Pessimistic NPV	-83066806.04
NPV_O_Malaysia	Malaysia Optimistic NPV	130632054.01
NPV_R_Malaysia	Malaysia Realistic NPV	26568660.77
NPV_P_Malaysia	Malaysia Pessimistic NPV	-46668692.23
NPV_O_India	Indian Optimistic NPV	155191260.75
NPV_R_India	India Realistic NPV	51592608.73
NPV_P_India	India Pessimistic NPV	-14873142.41
NPV_O_NA	North America Optimistic NPV	194589332.74
NPV_R_NA	North America Realistic NPV	95152145.42
NPV_P_NA	North America Pessimistic NPV	39153816.76
P_PL_B_Revenue_Major	Pessimistic one-year additional revenue for Product Line B	1089908843.07
Fix_Major_Failure	Cost to fix a major failure	75000000
Fix_Minor_Failure	Cost to fix a minor failure	30000000
P_PL_B_Revenue_Minor	Pessimistic 3-month additional revenue for Product Line B	272477210.77
percentage_lost	Percentage of revenue that the new site would make up	-0.10
R_PL_B_Revenue_Major	Realistic one-year additional revenue for Product Line B	932769418.20
R_PL_B_Revenue_Minor	Realistic 3-month additional revenue for Product Line B	233192354.55
O_PL_B_Revenue_Major	Optimistic one-year additional revenue for Product Line B	1263074113.51
O_PL_B_Revenue_Minor	Optimistic 3-month additional revenue for Product Line B	315768528.4

The Supply Chain Strategy Group at Company X reviewed the applied probabilities for this analysis. The realistic scenario was the most likely to occur when compared to the optimistic and pessimistic scenarios, hence the differences in these probabilities. The calculations for the expected revenue in case of a failure

were based on the "Global Minus APAC" sales in 2019. It was assumed that if manufacturing operations for Product Line B were expanded, the new location would be able to produce a certain amount of product that would have otherwise been produced at the current North American location, and initial estimates showed a 90% global revenue recovery for the facility design in all three locations (Malaysia, China, and India). The recovery costs ($75M for a major failure and $30M for a minor failure) include all operational changes that are required to support global demand for such an event (e.g., increased labor, logistics, project expenses), in addition to the costs required to remedy the issue at the North American location(s). In the end, the analysis confirmed that it is worth continuing to supply product from North America as opposed to expanding manufacturing operations in the APAC region.

References

Bai, J.B. and Da, G. (2011). Strategies for Trade Secrets Protection in China. *Northwestern Journal of Technology and Intellectual Property, 9*(7). Retrieved August 6, 2012 from http://scholarlycommons.law.northwestern.edu/njtip/vol9/iss7/1

Christodoulou, P. (2009). Tailored approaches to manufacturing footprint strategy. *CIM Briefing, 2.* Retrieved July 5, 2012 from http://www.ifm.eng.cam.ac.uk/uploads/Resources/Briefings/09_2_tailored.pdf

Christodoulou, P., Fleet, D., Hanson, P., Phaal, R., Probert, D., & Shi, Y. (2007). *Making the right things in the right places: A structured approach to developing and exploiting manufacturing footprint strategy.* Cambridge, UK: University of Cambridge Institute for Manufacturing. Retrieved July 5, 2012 from http://www.ifm.eng.cam.ac.uk/uploads/Resources/Reports/Footprint_Strategy.pdf

Coin News Media Group. (2012). *Historical inflation rates: 1914 – 2013, annual and monthly tables – U.S. inflation calculator.* Retrieved September 13, 2012 from http://www.usinflationcalculator.com/inflation/historical-inflation-rates/

Donoghoe, N., Gupta, A., Linden, R., Mitra, P., & Von Morgenstern, I.B. (2012, July). Medical device growth in emerging markets: Lessons from other industries. *In Vivo: The Business & Medicine Report*, 1-9. Retrieved June 6, 2012 from http://www.mckinsey.com/~/media/McKinsey/dotcom/client_service/Pharma%20and%20Medical%20Products/PMP%20NEW/PDFs/Medical_device_growth_in_emerging_markets_InVivo_1206.ashx

Dratler J. (1991). *Intellectual Property Law: Commercial, Creative, and Industrial Property.* New York, NY: Law Journal Seminars Press.

Ernst & Young. (2011). *Capturing Recall Costs: Measuring and Recalling the Losses.* Retrieved March 14, 2013 from http://www.ey.com/Publication/vwLUAssets/Capturing_Recall_Costs/$FILE/Capturing_recall_costs.pdf

Ernst & Young. (2012). *Incentives in ASEAN region 2012.* Retrieved January 27, 2013 from http://www.ey.com/Publication/vwLUAssets/Inaugural_edition_-_Incentives_in_ASEAN_region_2012/$FILE/Inaugural edition - Incentives in ASEAN region 2012.pdf

Food & Drug Administration. (2012, December 5). *Is the product a medical device?* Retrieved January 25, 2012 from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm

Frost & Sullivan. (2011 January). *Strategic Analysis of the Russian Pharmaceutical Market.* Retrieved January 29, 2013 from http://www.frost.com.libproxy.mit.edu/prod/servlet/catalog-download.pag?catid=M655-01-01-00-00

Frost & Sullivan. (2012 July). *Asia-Pacific Healthcare Outlook 2012 – 2015: Emerging Healthcare Opportunities.* Retrieved December 2, 2012 from http://www.frost.com.libproxy.mit.edu/prod/servlet/cio/9837-00-2C-01-01/9837+segment+40.pdf

Global Intellectual Property Center. (2012). *Measuring momentum: GIPC International IP index*. U.S. Chamber of Commerce. Retrieved December 3, 2012 from http://www.theglobalipcenter.com/measuring-momentum-the-gipc-international-ip-index/

Jorda. K.F. (2007). Trade Secrets and Trade-Secret Licensing. In A. Krattiger, R.T. Mahoney, L. Nelsen, et al. (Eds.), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (1st ed., pp. 1043-1059). Oxford, U.K.: MIHR & Davis, CA: PIPRA. Retrieved August 15, 2012 from http://www.iphandbook.org/handbook/chPDFs/ch11/ipHandbook-Ch%2011%2005%20Jorda%20Trade%20Secret%20Licensing.pdf

National Conference of Commissioners on Uniform State Laws. (1985). *Uniform Trade Secrets Act with 1985 Amendments*, 5. Retrieved December 2, 2012 from http://www.uniformlaws.org/shared/docs/trade%20secrets/utsa_final_85.pdf

Porter, M.E. (1985). *Competitive Advantage: Creating and Sustaining Superior Performance*. New York, NY: The Free Press.

Powell, B. (2012, May 28). Companies in China are struggling to hold on to talent. *Time Magazine*. Retrieved December 2, 2012 from http://www.time.com/time/magazine/article/0,9171,2115073-2,00.html

Simchi-Levi, D., James, P. P., Mulani, N., Read, B., & Ferreira, J. (2012). Is it time to rethink your manufacturing strategy? *MIT Sloan Management Review, 53*(2), 20-22. Retrieved November 12, 2012 from http://search.proquest.com/docview/914408095?accountid=12492

Simchi-Levi, D., Kaminsky, P., & Simchi-Levi, E. (2008). *Designing and Managing the Supply Chain: Concepts, Strategies and Case Studies*. New York, NY: McGraw-Hill/Irvin.

Steinle, C. & Schiele, H. (2008), "Limits to global sourcing? Strategic consequences of dependency on international suppliers: cluster theory, resource-based view and case studies", *Journal of Purchasing & Supply Management, 14*(1), 3-14. doi: 10.1016/j.pursup.2008.01.001.

Treleven, M., & Bergman Schweikhart, S. (1988). A risk/benefit analysis of sourcing strategies: Single vs. multiple sourcing. *Journal of Operations Management, 7*(3–4), 93-114. doi: 10.1016/0272-6963(81)90007-3

U.S. Energy Information Administration. (2012). *Annual Energy Outlook 2012: with projections to 2035*. U.S. Department of Energy. Retrieved September 13, 2012 from http://www.eia.gov/forecasts/aeo

XE Currency Tables. (2012). Retrieved September 13, 2012 from http://www.xe.com/currencytables/